OPTN Membership and Professional Standards Committee`
Meeting Summary
November 6-8, 2024
Virtual

Cliff Miles, M.D., Chair
Scott Lindberg, M.D., Vice Chair

Introduction

The Membership and Professional Standards Committee (MPSC) met virtually in both open and closed sessions on November 6-8, 2024, via Webex teleconference, to discuss the following agenda items:

1. MPSC Update Criteria for Post-Transplant Graft Survival Metrics Proposal
2. Pediatric Heart Pre-Transplant Mortality
3. Performance Monitoring Enhancement 2-Year Post-implementation Monitoring Report
4. Membership Requirements Revision Project
5. Report of Investigative Activities
6. Third Party/Procurement Update
7. Annual Review of Operational Rules and Monitoring Process
8. MPSC Transparency: Policy Referrals, Education, and Communication
9. Membership Issues
10. Performance Issues
11. Compliance Issues
12. Estimated glomerular rate (eGFR) Case Discussion

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

1. MPSC Update Criteria for Post-Transplant Graft Survival Metrics Proposal

OPTN contractor staff and the MPSC Chair reviewed the themes of public comment on the MPSC's Update Criteria for Transplant Program Metrics proposal and the discussion and recommendation of the Performance Monitoring Enhancement Subcommittee to request approval of the proposal without any post-public comment changes. The proposal received broad support in public comment. The public comment themes included:

- Supporters noted will decrease risk aversion and encourage acceptance of more complex donor organs and candidates.
- Support for no change to offer acceptance thresholds at this time.
- Concerns that this change without change to Scientific Registry of Transplant Recipients (SRTR) tiers and by payers will not change behavior.
- Some concerns that patient safety may be compromised, and post-transplant outcomes may worsen.
- Suggestion to consider changes to pediatric recipient post-transplant graft survival thresholds.

The small number of comments that addressed a potential change to pediatric recipient post-transplant graft survival were split. The Subcommittee recommended no change to the pediatric recipient post-transplant graft survival thresholds reconfirming the committee's rationale for this decision. The

rationales includes the difficulty determining statistically meaningful outliers because of the smaller number of programs and low volume of pediatric transplants, the need for closer monitoring of the transplant outcomes for children based on public perception, and additional important considerations supporting avoidance of more clinically complex donor organs for use in transplants in children that precluded changes to the metric thresholds to encourage use of these organs in pediatric recipients. The Subcommittee recommended that the data on alternative pediatric thresholds and additional explanation of the decision not to change the pediatric thresholds be included in the briefing paper.

Contractor staff also provided information on the performance improvement (yellow) zones and the number of programs that would fall within the yellow zone under various thresholds. The committee was asked whether they wanted to establish new yellow zone thresholds at this time or wait until after the proposal is approved by the OPTN Board of Directors. Additionally, the committee was asked if additional data would be helpful in considering the yellow zone thresholds.

Summary of Discussion:

Decision #1: The Committee voted to send the Update Criteria for Post-Transplant Graft Survival Metrics proposal to the OPTN Board of Directors for approval by a vote of 30 For, 0 Against, 1 Abstention.

Decision #2: The Committee decided to wait to address the thresholds for the performance improvement (yellow) zone until after consideration of the proposal by the OPTN Board of Directors and requested additional data.

Decision #1: The Committee voted to send the Update Criteria for Post-Transplant Graft Survival Metrics proposal to the OPTN Board of Directors for approval by a vote of 30 For, 0 Against, 1 Abstention.

The Chair requested that complex donor organ be defined in the briefing paper. One member asked whether this proposal should move forward without a change to the SRTR five-tier system. The MPSC Chair noted that making changes to the SRTR five-tier system is outside the authority of the MPSC and his personal opinion is that the MPSC should move forward to lead by example and hope others will follow. The SRTR Director responded that its role is to provide good data particularly to the patient community, on programs' outcomes but acknowledges that it is not uncommon for the SRTR five-tier system to be discussed as a barrier to increasing transplant. The SRTR is exploring, with its Advisory Committee, ways to switch, at least the initial display of the tiers from post-transplant outcomes to overall survival from listing. With no further discussion, the committee proceeded to a vote on the proposal.

Decision #2: The Committee decided to wait to address the thresholds for the performance improvement (yellow) zone until after consideration of the proposal by the OPTN Board of Directors and requested additional data.

The MPSC Chair requested data on whether the programs that received a communication advising them that they were in the yellow zone did better, worse, or the same in the next cycle. He suggests this data might provide information on the effectiveness of the yellow zone notification process. The Chair also asked about the contractor staff effort in notifying and fielding questions from programs that fall into the yellow zone. Contractor staff responded that it was a bit hard to measure the effort since new metrics have been added over time. She estimated that it took approximately two days to put together the memos and send the emails. She also added that the contractor performance staff have not received very much direct engagement from the programs that have received these memos. One

member asked whether there are any educational materials that are sent to the programs that fall within the yellow zone. contractor staff responded that the memo provides information about the available data reports, toolkit available on the OPTN website, and in the past, have informed them about the individual member focused improvement program (IMFI). The Chair suggested waiting until after the Board of Directors has considered the proposal to make a decision on the yellow zone. He suggested that waiting would give time for the members to provide more thought and consider ways to streamline the process to reduce contractor staff effort. The Committee will revisit the yellow zone thresholds at its December meeting.

2. Pediatric Heart Pre-Transplant Mortality

The MPSC found that a disproportionate number of pediatric heart programs were flagged for pre-transplant mortality. A SRTR representative presented that pre-transplant mortality models for pediatric heart programs include adjustment for four pulmonary artery (PA) pressures and these pressures are not reported in 45-55 percent of pediatric patients. Standard evaluation processes assume lowest risk for that element if not reported (least-favorable imputation). A discussion on November 1, 2024, with representatives of the SRTR and a group of pediatric cardiologists confirmed that the test is not standard of care in certain pediatric patients. Reasons for missing PA pressures included right heart catheterization not always being performed for pediatric candidates and divergent physiologies in pediatric heart transplant. In July 2024, seven pediatric heart programs were identified for elevated pre-transplant mortality and in the preliminary models for January 2025, five pediatric heart programs are identified. The SRTR found that the number pediatric heart programs identified can be impacted by how the missing PA pressures are handled.

Suggested long-term solutions would be to improve data collection on physiology of pediatric heart candidates and explore subsets where right heart catheterization data are more or less predictive of pre-transplant mortality. In the short term, these data tend to be highly missing or not meaningful in congenital heart disease patients or patients less than one year old. The least-favorable imputation method may not be suitable for these variables, because the missing data could be due to physiology and appropriate center practice, often in high-risk candidates. The SRTR's proposal for the January 2025 evaluations would be to include PA pressures in risk adjustment because they are predictive, but also include an indicator in the model for the pressure not being measured. When retroactively applied to the July 2024 evaluations, four programs were identified rather than seven.

The Committee discussed the SRTR proposal and stressed the importance of fine tuning the SRTR model. Committee members expressed concern that the model may not be able to appropriately adjust risk for pediatric heart patients due to their diverse physiology and anatomical variations. SRTR staff responded that they would take a broad assessment of all the data reported on these candidates and use it to build the best model possible. Contractor staff stated that additional data collection could be a referral to the OPTN Heart or Pediatric Committee.

The Committee voted to approve the SRTR's proposal for the January 2025 evaluations by a vote of 25 For, 0 Against, 1 Abstention.

3. Performance Monitoring Enhancement 2-Year Post-implementation Monitoring Report

OPTN contractor research staff presented results from the 2-year Performance Monitoring Enhancement (PME) post-implementation monitoring report. This report used auto-regressive integrated moving average (ARIMA) models fit to data pre-OPTN Board Approval of the PME policy to

forecast trends that would have been expected to occur post-Board Approval had the policy not been implemented. The Committee discussed these results and provided feedback as follows:

- Autoregressive integrated moving average (ARIMA) models may possibly induce wider confidence intervals in some cases. Is that something that can be validated? How does the ARIMA model affect the graft failure? Does it increase? Does the covid period affect the model/data any?

  Contractor staff responded that the data show confidence intervals were reasonable, although some could not be computed due to a small sample size. The ARIMA model puts more weight on more recent data, not necessarily historical data. Should we exclude the 2020 period? That is a good point. Moving forward as more follow-up time accrues, we could possibly shift the cohort to start after 2020.

- Did the model take into account the changing demographics, such as DCD, High KDPI, machine preservation, NRP, other preservations, etc. How would that affect the analysis?

  Contractor staff responded that donor characteristics were not adjusted for, but some analyses were stratified by these characteristics (e.g., DCD, donor age, etc.). Stratified analyses are available in the full report, which was provided in the meeting packet.

  The SRTR staff elaborated on the Covid era. They did not see a lot of evidence that it would change a lot of those trends or impact. Did not notice anything that would move the predictive interval much. Could take into account the suggestion to include some of the donor demographics/characteristics.

  Contractor Staff: Appreciate the feedback. Will consider. In agreement.

- A Committee member expressed interest in donor age component, noting that the largest rise occurred in donors above the age of 50, however donors aged 18-34 stayed in the expected range. The non-use rate went up as the expected transplant rates increased. It seems like it would be helpful to consider O-to-E (observed-to-expected) analyses to account for some of these donor factors.

  OPTN staff acknowledged the great suggestions.

4. Membership Requirements Revision Project

Contractor staff reviewed the project plan for the Membership Requirements Revision project and updated the committee on the feedback received from Health Resources and Services Administration (HRSA) on the MPSC proposal that was pulled from the summer 2024 public comment cycle. Following the HRSA request that the proposal be pulled from public comment in July, the MPSC ceased all work on the Membership Requirements Revision project. HRSA later shared with the OPTN that its concerns with the proposal were related to the application and review process in Appendix A. HRSA did not have concerns with the proposed revisions to the membership requirements for OPOs, transplant hospitals and transplant programs contained in Appendix B and Appendix D. MPSC Leadership indicated that the

revisions to the OPTN membership requirements were a priority for the committee and HRSA agreed that work on the membership requirements could resume.

Contractor staff reviewed an updated proposal that removed the proposed *Appendix A: Membership and Designated Transplant Program Application and Review* and any references to the proposed review process in Appendix D. Appendices E – K were removed from the proposal as the only proposed revisions were references to the proposed review process. Finally, the proposed revisions to the definition of the Membership and Professional Standards Committee in Appendix M were removed. Other than these described removals, the proposal is the same as that approved by the MPSC for summer 2024 public comment.

Summary of Discussion:

Decision #1: The Committee voted to approve the release of the Update Membership Requirements for OPOs, Transplant Hospitals and Transplant Programs proposal to winter 2025 public comment by a vote of 28 For, 0 Against, 0 Abstentions.

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One member suggested that the vote on the proposal be delayed for further review since the previous proposal was approved for public comment by the committee prior to July 1 when half the committee turned over. The member provided an example of a provision that he felt was outdated and inconsistent with current allocation policy and practice. The Chair acknowledged that the work on the proposal has been over a number of years because of holds being placed on the project but also noted that the language of the proposal has been reviewed by several iterations of the MPSC. Staff noted that if the committee wants to postpone a vote on the proposal to review it further, the proposal will not meet the timeline for winter 2025 public comment. The Chair noted the tradeoff for postponing the vote is timing and addressed recent application reviews, particularly pancreas, where the requirements are hampering the ability of hospitals to staff programs. The Chair also noted that the committee would have the capability to make edits to the proposal post-public comment and asked the new committee members if they felt comfortable voting on the proposal today. A second-year member of the committee noted that the committee reviewed the proposal in detail earlier this year. The majority of new members who spoke were comfortable with voting on the proposal.

Following the vote, Contractor staff requested volunteers for the Membership Requirements Revision Subcommittee to resume work on the organ-specific key personnel training and experience phase of the project.

5. Report of Investigative Activities

Contractor staff supplied a summary of investigative activity for October 2024 and a rolling four-month report from July 2024 through October2024. The reports included the number of reports staff received, modes of receipt, reporting and subject, member type, general classification of the issue, how many cases staff referred to the MPSC were closed without sending them to the MPSC, or are still actively investigating. The reports are received mostly through the patient safety portal.

During the month of October, the OPTN received 49 patient safety reports. Most of the reporters were from transplant hospitals. During October, ten reports were not forwarded to MPSC for review because they were investigated and either referred to other OPTN contractor departments that monitor that

issue, determined to be outside of OPTN purview, did not violate OPTN obligations, or were not a patient health or public safety issue.

Likewise, during the 4-month review period 85 cases were investigated by contractor staff, and it was determined that the members did not violate OPTN obligations or pose a threat to patient health or public safety, so they were not referred to the MPSC. Most of the cases were referred to other departments for review, some were duplicates, and others were submitted by anonymous sources who could not be reached to provide additional information for the investigation.

The 4-month data continued to show the most common reason for not referring a case to the MPSC at the conclusion of an investigation is that staff found no evidence of noncompliance with OPTN policies or bylaws, including threats to patient safety. No significant trends in the primary classifications of reports have been observed in the data.

Contractor staff are working on additional classifications to further stratify the cases now grouped under "other."

Discussion

Committee members provided feedback and had questions as follows.

- A Committee member observed that the majority of reports come from transplant hospitals, yet more OPOs are being investigated. Other committee members noted that the hospitals tend to have a larger staff and more people who can report. It may be because they tend to report about OPO activities, and that OPOs have more OPTN regulatory reporting requirements. Additionally, transplant hospital staff may be reporting directly to the OPTN instead of taking their concerns directly to the OPO in question. This could be a result of broader allocation and sharing and less direct communication between the hospital and OPO. Transplant hospitals see all of the OPO's work, but OPOs do not see the transplant hospitals processes after organ placement. This could also contribute to the imbalance between hospital reporting and OPO investigations.
- There was general agreement that the number of policies that the OPOs must adhere to is larger than those of the transplant hospitals, so it is not bi-directional.
- A committee member pointed out that a portion of the cases reviewed during this meeting were from mid to late 2023 and expressed concern about the case turnaround time and the need for more real time review. Staff explained that staff turnover has resulted in a backlog and are developing comprehensive case metrics, further defining case priority standards, and seeking recommendations from the Committee to better understand their needs.

6. Third Party/Procurement Update

The MPSC will develop recommendations for potential MPSC referrals to other OPTN committees or recommendations for other OPTN committees to consider in current projects related to participation of third-party vendors in procurement, procurement standards, particularly related to use of perfusion technology and normothermic regional perfusion (NRP), procurement surgeon standards, and additional data collection related to procurement. Contractor staff reviewed ideas that were shared by committee members during the July meeting as well as the current projects underway by other OPTN committees.

Initially, Contractor staff reviewed the data elements included in the OPO Committee's Enhancements to OPTN Donor Data and Matching System Clinical Data Collection proposal, which has been approved by the OPTN Board and is awaiting implementation. The OPO Committee is also undertaking a few projects including a Machine Perfusion Data Collection project, Review of DCD Policies project, and the MPSC referral of procurement team responsibilities policy. The OPO Committee plans to release a

proposal for collection of machine perfusion data for public comment next summer. An initial list of data elements has been generated but they are still developing the final proposal to gather data from OPOs and transplant hospitals. The review of DCD policies project involves a comprehensive review of all DCD policies to ensure they are consistent with current practice and to evaluate the need for machine perfusion and NRP policies. The previous MPSC referral to outline the responsibilities of the procurement team is currently in the queue behind the machine perfusion data collection project.

The Operations and Safety Committee has two relevant current projects; deceased donor testing requirements project, which has an MPSC subject matter expert as a part of the work group and a project on standardizing the practice in the use of NRP in organ procurement, which was established pursuant to an OPTN Executive Committee directive from October 2024.

The contractor staff provided a summary of MPSC member feedback that was provided through email. The following questions were asked:

- What data needs to be collected to get a better understanding of the issues?
- Should recommendations for development of guidance/effective practice documents be referred to other OPTN committees?
- What policy changes would you suggest to address the concerns raised by the MPSC?

Some of the information and feedback provided included collecting more data on what machine perfusion is used intra-operatively and post-operatively and capturing data on organ acceptance/procurement and tracking the reports to the FDA. This data could help the Committee better understand the issues.

Recommendations for the development of effective practices included ensuring the roles and responsibilities during procurement are aligned with safety and compliance, effective practices on machine perfusion usage, and providing procurement personnel standards. The Committee also provided feedback on potential policy changes to address concerns including development of a hierarchy/process for resolving conflicting expectations; updating packaging and labeling requirements to address post-procurement machine perfusion; updating allocation policy for organ “rescue” intra-operatively to accommodate rapid reallocation as a standard, not an exception; reporting of machine perfusion failure to OPTN and FDA when it results in the loss of an organ; and requiring reporting of provider issues during procurement.

MPSC Discussion

The contractor staff asked the committee for the next steps and guidance on how to address existing committee projects and if there was a want or need for MPSC involvement.

A Committee member asked if there was any communication between the OPO Committee and the Operations and Safety Committee. There was concern that there was some overlap in the project material. Contractor staff confirmed that it is safe to assume that there is cross-committee collaboration.

A Committee member had a question regarding machine perfusion data collection. They asked if all of the information that has been discussed at the MPSC meeting is shared with the OPO Committee so that they understand the context or should an MPSC member be a consultant to share that level of detail. There was also a question regarding MPSC representation on other committee projects. The contractor staff asked if the full committee wishes to have MPSC representation on any of these projects and/or share certain information about MPSC discussions of NRP and procurement issues discussed during MPSC meetings. The committee member agreed that acting as a consultant to the other committees

could be helpful to share insights and a level of detail of what is being discussed during the MPSC meetings. Another member agreed with the above comment.

A Committee member agreed that there is a lot of overlap between projects. They suggested a multi-level work group with several subcommittees to identify focus areas/categories and have a collaborative conversation. Another committee member agreed that there is a need for alignment between the various committees and projects and suggested that having a sponsoring committee could help with the extra work that might spin up. The contractor staff responded that the committees listed are sponsoring the project and likely collaborating with other committees. The contractor staff shared that policy colleagues have noticed some overlap and there is a plan to take it back to them to see if there are any other opportunities for collaboration. A committee member suggested that having one MPSC member participate could be beneficial.

A Committee member suggested inclusion of a "good citizenship with third party vendors" category in data collection that highlights the issues that occur between procurement personnel. A committee member shared a concern that not all of the procurement participants fall under the purview of the MPSC. Another committee member responded that the issues fall under patient safety. Another committee member suggested collecting data on surgical damage. A committee member shared that at least one of the third-party procurement vendors requires that the OPTN contracting member must use only the third-party perfusions surgeons to procure the organs in order to use their technology.

Summary

The Committee recommended that the OPTN conduct an evaluation of the overlap of the multiple projects sponsored by the OPO and Operations and Safety Committees to streamline the efforts on these topics. The Committee expressed an interest in MPSC representation on other committee projects related to third parties, NRP, and procurement standards in order to share learnings from the information available to the MPSC on the types of issues that arise.

7. Annual Review of Operational Rules and Monitoring Process

Over time, the MPSC has approved processes and operational rules to make their workload smoother and to allow committee members to focus their efforts on the most significant and impactful issues. In the past, the Committee approved these processes individually and they have remained in place unless a policy, bylaw change, or process improvement created a need to update them.
Beginning in 2022, the Committee was asked to review all approved rules and processes annually. This review is intended to increase communication and confirm that all existing rules are relevant. Staff presented each rule, providing time for the Committee to deliberate or suggest changes. A summary of each one follows.

Decision #1: The Committee approved all existing operational rules as presented for another year by a vote of 28 Yes, 0 No, 0 Abstentions.

Overall processes

- Case Review Process: Currently, MPSC members review cases through the OPTN computer system. Staff create reports and assign three or four MPSC members to an ad hoc subcommittee to review each case. When selecting MPSC members for each subcommittee, staff consider the nature of the case and appropriate subject matter expertise, any potential conflicts of interest,

and committee members' availability. Staff may try to gain consensus prior to assigning the case to an agenda.
A committee member asked questions about the use of the discussion option on cases posted in case review system within the OPTN Computer System and remarked that you had to vote on the case before you could see the entire discussion thread, rather than using it to discuss the case before voting. Contractor staff advised the member to either email the analyst assigned to the case or vote on the case and request the additionally needed information in the comments. Staff can later reset the vote so that a member can vote again if new information is received that satisfies their concern. Prior to voting, additional discussion with the other reviewers can be held via email. Another member noted that the documents are sometimes heavily redacted and challenging to review. When that happens, they should contact the analyst with their questions.

- Process For Member Waiving Interview: As outlined in the OPTN Bylaws, Appendix L *(Reviews and Actions*), the MPSC may offer a member an interview. If a member waives an interview, staff bring the issue back to the Committee to confirm the next steps. The MPSC will review the case again, including the members' waiver of its interview, to confirm the action for the issue as well as any requested documentation submissions and aspects of monitoring the Committee may want. Committee members supported this process and did not have any questions.

- Hearing Format: After an interview, the member may be entitled to a hearing. During a hearing, the OPTN and member each provide a presentation and no less than 60 minutes each is allowed. The hearing is set up in a way that counsel is not necessarily required. The OPTN presentation covers facts of the case, applicable OPTN obligation(s), process steps, and the MPSC's rationale for its recommendation. The Member's presentation focuses on MPSC concerns and requests, additional progress since the last submission, and any other information the member would like to include. The MPSC question-and-answer session is focused on addressing the committee's concerns. After initial deliberation, MPSC may invite the member back for additional clarification. At the conclusion, the MPSC will give reasons for its decision tied to the issue, presentation, and responses. The Committee did not have any questions or concerns about this process.

<u>Performance Related</u>

- Sending Initial Performance Inquiries: The MPSC approved an operational rule to automatically send an initial inquiry to members who are newly identified for performance review when the data is available, without a committee vote. This practice may be able to receive their inquiries earlier and that may provide them with more time for preparing their response and for the committee to conduct its review. The Committee had no questions, concerns, or suggested changes for this operational rule.

- Inactivity Review Guidelines: The OPTN Bylaws, Appendix D.11.A (*Review of Transplant Program Functional Activity, Functional Inactivity*) outline requirements for transplant program activity. The Committee previously approved the following rules to determine which members receive an initial inactivity inquiry: Is program currently active? Has the program been inactive for one year? Is the program currently under review? Has the MPSC released the program from inactivity review in the last two meeting cycles? Did the program receive zero offers or have zero candidates on the waitlist? If the answer to any of these questions is yes, staff do not send an inquiry.

A Committee member asked if a program were under review for another issue, such as outcomes, would they still be sent an inactivity inquiry, or would it be assumed that issue would be addressed as a part of the other review. Staff confirmed that they would still receive the inactivity inquiry.

- Pre- and Post Transplant Outcomes Review Guidelines: For transplant program outcomes, the MPSC also approved the same criteria as described in the functional inactivity section above and would not send a new inquiry if any of these criteria are met.
  Specifically, Is the program currently active? Has the program been in an active status for one year? Is the program currently under review? Was the program released from review prior to the last two meeting cycles?

  A member asked about not sending new inquiries to programs that had more recently been under review and released for any of the metrics. Staff explained that the committee likely would have already reviewed the more recent data as a part of its earlier inquiry since it reviews the current information and not just the cases included in the initial cohort. There was a brief discussion about the time frames for not sending new inquiries and they could be relooked at for each metric due to the lag time on the various data sets.

Application Related

- Late Key Personnel Changes: The OPTN Bylaws require members to notify the OPTN Contractor of a change in key personnel, specifically a primary physician, primary surgeon, laboratory director, technical supervisor, general supervisor, or clinical consultant. According to the first portion of this rule, if a member notifies the OPTN late of a key personnel departure but submits an application at least 30 days before the current person departs, staff will document and close the issue. Staff will educate the member on the late notification requirements. However, if the member fails to notify the OPTN within seven days after the hospital learned of a key personnel departure and fails to submit a key personnel change application at least 30 days before the current key personnel departs, the application will be posted for MPSC review. Lastly, the rule states that if a member reports a change late a second time, the case is posted for reviewers. The Committee had no questions or concerns about these rules.

- Reviewing Key Personnel Change and Non-Institutional Member Renewal Applications: To reduce the committee members' workload, transplant program Key Personnel change applications and Non-Institutional Member renewals that clearly meet the OPTN Bylaw requirements are put directly on the consent agenda for approval. The Committee had no questions or concerns about these rules.

- Application Rejections on the Consent Agenda: If reviewers unanimously agree to reject an application after review, that decision is placed on the consent agenda. This operational rule was put in place after the Committee had extensive discussions about applications that clearly did not meet the OPTN Bylaw requirements, which the MPSC has no option to approve. The Committee had no questions or concerns about this rule.

Compliance Related

- Survey Evaluation Tool (SET) Implementation and Update: The SET is used to determine whether a site survey is closed with no follow-up, a focused desk review of certain policies is needed, or the survey report should be sent to MPSC reviewers. The tool separates policies reviewed into

categories, based on the potential risk to patient safety. If a member does not meet the required compliance thresholds, staff automatically conduct a desk review of that policy after six months. The MPSC evaluates the routine review and the first desk review with the SET and moves forward with that recommendation. The MPSC will review any second desk review results and any reviews with serious concerns about patient safety, compliance, or corrective action plans. The Committee did not have any concerns about this operational rule.

- Closing Self-Reported Issues with No Action: In 2021, to encourage OPTN member reporting of potential patient safety issues, the MPSC approved an operational rule to place member self-reports on the consent agenda with a recommendation to close the case with no action, if the self-report included an appropriate Root Cause Analysis (RCA) and Corrective Action Plan (CAP), and the member had no significant MPSC compliance history. The Committee always has the option to pull a case from the consent agenda for further review. The MPSC agreed to continue the operational rule.

First Time Noncompliance Rules

- Late OPTN Report of Disease Transmissions: OPTN Policies 15.4 (*Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions*) and 15.5 (*Transplant Program Requirements for Communicating Post Transplant Discovery of Disease or Malignancy*) require OPOs and transplant programs to notify the OPTN and other OPOs and transplant programs, if they have certain specific information about or suspicion of a potential disease transmission between a donor and recipient. For members that report appropriately to other members but miss reporting to the OPTN, contractor staff request the results of any RCA and CAP. If the member has no significant history of late reporting and the RCA and CAP appropriately address the issue, the case is closed with no action. Any subsequent cases will go to the MPSC for review and will include information on the first case involving late reporting. When the MPSC approved this rule, they also added that the "first time" rule involves a rolling three-year period, since that is the time frame staff typically apply when reporting on a member's "compliance history" with the MPSC.

  A Committee member asked if one party reports the issue (i.e. an OPO) does the transplant program still need to report the same issue to the OPTN. Contractor staff clarified that Policy 15 addresses this issue. Staff responded that as long as the first member has reported properly then the second member does not need to report the same case. The OPTN may follow up with all involved members.

- Waitlist Inactivity: Programs are reviewed for patient notification of periods of waitlist inactivity according to OPTN Bylaws Appendix D.12.B (*Patient Notification Requirements for Waiting List Inactivation*). Members are required to notify patients when inactivating their waitlist for more than 14 consecutive days or more than 28 cumulative days in a calendar year. Contractor staff receives a report and verifies that members notified their waitlisted patients. If they do not follow the requirements, members must implement a CAP. A first-time occurrence of noncompliance will not be forwarded to the MPSC for review. If a second event of noncompliance is identified, staff will gather documentation from the member and provide all documentation from both events to the MPSC for review. The Committee did not have any concerns about this operational rule.

- Vessel Storage: OPTN Policy 16.6.B (*Extra Vessels Use and Sharing*) prohibits members from storing extra vessels if the donor tested positive for human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) according to specified tests. The current operational rule in place includes automatically closing a member's first instance of storing prohibited vessels. Should the member store any prohibited vessels again, staff will forward the information, including the first instance, to the MPSC for review. The "first time" resets on a rolling three-year period. The Committee did not have any concerns about this operational rule.

- Living Donor Recipients Not Registered on Waiting List: Living donor transplant recipients are required to be registered on the waiting list according to OPTN Policy 3.4.C *(Candidate Registrations)* even if a program only intends to use a living donor organ for that recipient and is not looking for a deceased donor match for that recipient. This rule would automatically close the first time that a member failed to register a recipient of a living donor transplant on the waiting list. The member would be advised that the MPSC expects them to implement their plan to prevent the issue and any additional instances of the member failing to register a living donor recipient on the waiting list will be forwarded to the MPSC for review. The MPSC's review of the second instance will include the initial violation. The "first time" resets on a rolling three-year time period. The Committee did not have any concerns about this operational rule.

The Committee approved the operational rules for another year by a single vote of 28 Yes, 0 No, 0 Abstentions. Changes may be brought back to the committee for consideration during any scheduled meeting.

8. MPSC Transparency: Policy Referrals, Education, and Communication

Referrals

Contractor staff began by reviewing updates on previous policy referrals sent by the MPSC. The Committee received updates on each referral that has made progress since the July meeting and omitted the referrals that are either paused or completed. Afterward, the Committee discussed two new potential referrals:

- Improved Pediatric Heart Data Collection

  During the MPSC's earlier discussion on pediatric heart pre-transplant mortality data with the SRTR, it became evident that the solution identified was a short-term solution, but a long-term solution should be identified by the relevant policy development Committees. The MPSC identified the Heart and Pediatric Transplantation Committees as the appropriate recipients for this referral and identified a moderate urgency level since there is a short-term solution in place. The MPSC would like the Committees to refine the data to make the model more applicable to different disease diagnoses, age groups, etc. to more accurately reflect the patient's pre-transplant mortality risk. An MPSC member and SRTR staff voiced their willingness to support the Heart and Pediatric Committees as they take on this referral.

- Clarify Discrepant ABO Typing Post-Transfusion

  During closed session discussions, the MPSC identified a gap in OPTN Policy 2.6.C (*Reporting of Deceased Donor Blood Type and Subtype)* where there may be a need for more prescriptive policy language to ensure that the blood typing discrepancy is appropriately resolved. The MPSC felt that an OPO could have a protocol that addressed these issues and appropriately follow the protocol, but it is still possible that the protocol itself could fail to best handle the discrepancy

and potentially lead to an incompatible transplant. Member expressed specific concern that in the event of blood typing or subtyping discrepancies post-mass transfusion, an OPO protocol be followed that result in allocating an organ by the incorrect blood or subtype. It was suggested that a potential solution could be requiring molecular testing for mass transfusion donors who have discrepant blood typing results.

Since mass transfusions are common and blood typing and subtyping discrepancies have continued to be a recurring issue, the MPSC felt that this gap in policy has the potential to impact every donor and recipient. As such, members agreed that this referral has a high level of urgency. The MPSC considered the previous pre/post-transfusion check box referral that was sent to the Operations and Safety Committee (OSC) and this referral being a potential extension of the previous one. However, given the potential for molecular testing and a previous interest in it from the Histocompatibility Committee, members also recommended referring to them. Also considering the OSC's current workload and limited capacity, the MPSC agreed that a joint referral to the Histocompatibility and OSC would be an appropriate next step. Contractor staff will work with MPSC leadership after the meeting to frame this referral as an expansion and redirection of the previous referral to a joint one.

MPSC Educational Initiatives

MPSC committee members have participated in recent educational initiatives including community webinars and presentations at the 2024 Transplant Quality Institute (TQI) conference. Members shared positive experiences at the Transplant Quality Institute (TQI) including support of the MPSC's work and how the perception of the MPSC is evolving as a collaborative entity. The Chair mentioned that he was asked at TQI if the MPSC has any mechanism for tracking members or individuals in the community that have posed previous patient safety concerns. This topic has been discussed internally by the MPSC before and members recognized that creating such a tool could help improve the committee memory of the MPSC given the short-term cycle and in recognizing patterns in patient safety, but that creating such a tool could also be problematic in terms of liability and impacting the future of individuals. The committee members agreed that there should be follow-up on this discussion with the inclusion of legal counsel.

MPSC Chair Email and Community Communications

OPTN Contractor staff shared updates on MPSC transparency and public disclosure including updates on the member monitoring and compliance resources on the OPTN website. They asked what committee members wanted to share with the community from this week's meeting in the MPSC Chair Email.

The Chair suggested a specific call out continued attention to the interaction of massive transfusions with ABO typing and subtyping given the potential referral that was discussed.

Another member recommended recognition of the community for all of the hard work they have put in now that the eGFR reviews have been completed. A member agreed and wanted to include a reminder that new patients need to continue to be reviewed for qualifying eGFR waiting time reinstatement, and that a potential best practice is to discuss that possibility with patients at annual visits.

Several members wanted to highlight the project work that the MPSC is continuing to do regarding performance metrics and membership revisions.

A committee member suggested including information about allocation of out of sequence and interaction with trying to identify hard-to-place organs, alongside a reminder of MPSC's continued review and member's responsibility to follow the match run.

The issue of living donor patient safety events was raised and a committee member wanted to include the necessity for heightened awareness on this topic. One common thread was to make sure member processes include review of all testing that is completed. Another member noted that it should include testing completed by outside providers and those performed for paired exchanges. Several members highlighted the importance of reviewing both diagnostic and source documentation.

MPSC Transparency Discussion

A Committee member began by sharing how helpful the information shared at TQI was, particularly regarding how to respond to an MPSC inquiry to aid the Committee in conducting a thorough investigation, and how it would be great to share that with a broader audience. Another member agreed and wished there were more forums for sharing information from the MPSC at provider focused meetings outside of the Chair Emails. A member was curious if the MPSC ever received feedback from members about their experiences interacting with the MPSC, or if there is an opportunity to do so. It was noted that a significant portion of the MPSC's work consists of simple processes such as personnel changes, and it could be beneficial to the community and to streamlining the MPSC's work to provide best practices or guidelines for those high volume, simple items. Several members suggested applying to participate in large industry conferences such as ATC, AOPO, AST, ASTS, and the Alliance.

9. 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 during closed session. The Committee reviewed and approved the consent agenda by a vote of 23 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 December 2024 meeting.

- Approve 4 new transplant programs
- Approve 1 new public organization member

The Committee also reviewed and approved the following:

- 4 Applications for new key personnel for Transplant Programs or Components
- 44 Applications for changes in key personnel for Transplant Programs or Components
- 6 Applications for changes in key personnel for Histocompatibility Laboratories
- 1 Program Coverage Plan for a change to single surgeon coverage

Additionally, the Committee received notice of member and program withdrawals, OPO key personnel changes, and discussed an application in closed session.

10. Performance Issues

For transplant programs under review for lower than expected 90-day graft survival rates and 1-year graft survival conditional on 90-day survival rates, the Committee approved the continued monitoring of 30 transplant programs: three heart programs for 90-day, two heart programs for 1-year conditional, and one heart program for 90-day and 1-year conditional graft survival; four kidney programs for 90-day, three kidney programs for 1-year conditional; six liver programs for 90-day, four liver programs for 90-day; four lung programs for 90-day, and one lung program for 1-year conditional; and one pancreas program for 90-day, one pancreas program for 1-year conditional. Additionally, the Committee

approved the release of monitoring of eight transplant programs: two heart programs for 1-year conditional; one kidney program for 90-day, one kidney program for 1-year conditional, and one kidney program for 90-day and 1-year conditional graft survival; one lung program for 90-day, one lung program for 1-year conditional; and one pancreas program for 90-day.

For transplant programs under review for offer acceptance, the Committee approved the continued monitoring of 19 transplant programs: 11 kidney programs, three liver programs, and five lung programs. Additionally, the Committee approved the release of monitoring of five transplant programs: three kidney programs, and two liver programs.

For transplant programs under review for pre-transplant mortality, the Committee approved the continued monitoring of nine transplant programs: five heart programs, two liver programs, and two lung programs.

For transplant programs under review for functional inactivity, the Committee approved the continued monitoring of one lung program and one pancreas program.
The Committee approved the consent agenda by a vote of 24 For, 0 Against, and 1 Abstention.

The Committee also discussed cases in closed session.

11. Compliance Issues

The Committee reviewed a consent agenda consisting of 16 transplant programs that had undergone a focused desk review during this cycle, including one heart program, four kidney programs, two living donor kidney components, four liver programs, two lung programs and four pancreas programs. The Committee released 13 of those programs from monitoring and recommended follow-up focused desk reviews for three programs, one of which was issued a Notice of Noncompliance for continued noncompliance. The Committee also reviewed 18 OPOs and one transplant program for allocation errors, all of which were closed with no action. The Committee reviewed 49 case investigations during this cycle, consisting of member complaints or self-reported potential policy violations. The Committee issued 24 Notices of Noncompliance and closed 25 issues with no action, 14 of which were closed for self-reporting. In addition, the Committee reviewed nine reported living donor events this cycle, five of which were on the consent agenda. Two events were aborted nephrectomies, one of which was reported within required timeframes and closed with no action, and one which was issued a Notice of Noncompliance for late reporting. There were three living donor redirections; two events were reported on time and closed with no action and one Notices of Noncompliance was issued for late reporting.

The Committee approved the consent agenda by a vote of 25 Yes, 0 No, and 2 Abstentions.

The Committee also discussed cases in closed session.

12. Estimated glomerular rate (eGFR) Discussion

The Committee continued its review and monitoring for appropriate implementation of OPTN Policy 3.7.D *(Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations)* during closed session. All members have been reviewed and determined to be in compliance.

Upcoming Meetings

- December 13, 2024, 2-5pm, ET
- January 24, 2025, 1-4pm ET
- February 21, 2025, 1-4pm, ET
- March 4-6, 2025, TBD – virtual or in person
- March 28, 2025, 1-4pm, ET
- April 25, 2025, 11am-2pm, ET
- May 22, 2025, 11am – 1pm, ET
- June 27, 2025, 11am-2pm, ET

Attendance

- **Committee Members**
  - Mitzi Barker
  - Megan Bell
  - Kristine Browning
  - Christopher Curran
  - Chadrick Denlinger
  - Amishi Desai
  - Nahel Elias
  - Chad Ezzell
  - Sander Florman
  - Roshan George
  - Darla Granger
  - Dipankar Gupta
  - Shelley Hall
  - Richard Hasz
  - Kyle Herber
  - Michelle James
  - Christy Keahey
  - Lindsay King
  - Kevin Koomalsingh
  - Kevin Korenblat
  - Peter Lalli
  - Raymond Lee
  - Scott Lindberg
  - Maricar Malinis
  - Deborah Maurer
  - Luis Mayen
  - Clifford Miles
  - Saeed Mohammad
  - Lloyd Ratner
  - Deirdre Sawinski
  - Malay Shah
  - Nirmal Sharma
  - Zoe Stewart Lewis
  - Carrie Thiessen
  - James Yun
- **HRSA Representatives**
  - James Bowman
  - Marilyn Levi
  - Raymond Lynch
  - Arjun Naik
  - Kala Rochelle
- **SRTR Staff**
  - Ryo Hirose
  - Grace Lyden
  - Jonathan Miller

    - Jon Snyder
    - Bryn Thompson
    - David Zaun
- **UNOS Staff**
    - Anne Ailor
    - Robert Albertson
    - Sally Aungier
    - Matt Belton
    - Torry Boffo
    - Tyrone Brown
    - Jadia Bruckner
    - Tameka Butler
    - Elinor Carmona
    - Tommie Dawson
    - Robyn DiSalvo
    - Nadine Drumn
    - Jon Dyer
    - Laureen Edwards
    - Katie Favaro
    - Liz Friddell
    - Michelle Furjes
    - Jasmine Gaines
    - Shavon Goodwyn
    - Caroline Hales
    - Asia Harden
    - Houlder Hudgins
    - Elias Khalil
    - Lee Ann Kontos
    - Jessie Kunnamann
    - Krissy Laurie
    - Ellen Litkenhaus
    - Amy Minkler
    - Heather Neil
    - Delaney Nilles
    - Jacqui O'Keefe
    - Rob Patterson
    - Rick Poole
    - Emily Powell
    - Shawn Richman
    - Liz Robbins Callahan
    - Melissa Santos
    - Laura Schmitt
    - Erin Schnellinger
    - Sharon Shepherd
    - Courtney Skeen
    - Sarah Stevenson
    - Stephon Thelwell
    - Melissa Tisdale

    - Betsy Warnick
    - Trevi Wilson
    - Claudia Woisard
    - Emily Womble
    - Hobie Wood
    - Hollie Woodcock
    - Karen Wooten
- **Other Attendees**
    - None