OPTN Membership and Professional Standards Committee
Meeting Summary
July 23-25, 2024
Detroit, Michigan

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

Introduction

The Membership and Professional Standards Committee (MPSC) met in person with a virtual option in both open and closed sessions on July 23-25, 2024, to discuss the following agenda items:

1. HRSA Introductory Remarks
2. Membership Requirements Revision
3. Preparing for Regional Meetings
4. HRSA Remarks Regarding Membership Requirements Revision
5. Performance Monitoring Enhancement Update
6. Continuous Distribution Update
7. Expeditious Task Force (ETF) Updates and Progress
8. Network Operations Oversight Committee (NOOC) - General Update
9. MPSC Transparency: Policy Referrals, Education, and Communication
10. Report of Investigative Activities
11. Membership Issues
12. Performance Issues
13. Compliance Issues
14. Estimated glomerular rate (eGFR) Case Discussion

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

1. HRSA Introductory Remarks

The Deputy Director in the Health Resources and Services Administration (HRSA) Division of Transplantation introduced himself and thanked committee members for their tireless work to ensure patient safety, compliance, monitoring, and equity. He recognized their tremendous commitment on top of their work in the transplant community and expressed HRSA's appreciation to both new and returning members.

He provided background on HRSA and its involvement including NOTA and the Final Rule. He explained that the Secretary of Health and Human Services (HHS) has delegated oversight to HRSA, which is handled by his division. He briefly described the OPTN Modernization Initiative that has a goal to develop new contracts and contractors to support the OPTN operations. There will be a separate entity and contractor to support OPTN Board of Directors and they are still working through the details of whether the Operations contractor or the one for Board Support will provide support to MPSC.

HRSA has been evaluating itself to identify shortcomings and has identified the MPSC as a priority committee under the OPTN Modernization Initiative because of its focus on patient safety. HRSA will continue to be involved in informal discussions, peer visits, etc. HRSA is committed to overseeing

MPSC's case process and workload and is increasing capacity to keep pace with endless activities of the MPSC.

He pointed out that some members in the community and public are unaware of HRSA's involvement and role in the transplant system. Hopefully, the MPSC sees the benefit of HRSA's engagement and noted that it retains the ability to direct an investigation at any time through the Secretary of HHS' authority.

HRSA is continuing to evaluate how the contractor intakes and triages complaints and patient safety issues to understand what goes to the MPSC and what does not and why. HRSA is also interested in MPSC's compliance review of allocations out of sequence and the processes for reviewing allocations out of sequence on a consent agenda, operational rules for reviewing these cases, variances, and rescue pathways and how the MPSC is handling this process. HRSA will be hiring additional staff to support its efforts.

He cited the eGFR project as a good example of MPSC and HRSA collaboration as we work together to maintain equity in access. HRSA appreciates MPSC's efforts to gather additional information and work to benefit patients.

Following his remarks, the Deputy Director took questions from the committee.

The Chair asked if HRSA had concerns about their presence impacting the ability to get accurate information during the interviews conducted during peer visits? He responded that he was aware that the question had come up, but HRSA hopes that it does not inhibit the process. There are people in the community who are unaware of HRSA's role so hopefully they will have a better understanding of HRSA's oversight and remain open to the MPSC's feedback

The Vice Chair shared that he had participated in peer visits both with and without HRSA representatives and he did not think that it negatively affected the engagement during the interviews, and they brought beneficial questions.

Another Committee member observed that the Deputy Director mentioned being on site allows HRSA to get information quicker than waiting for MPSC findings, but most often many of these cases come back to the full MPSC for consideration and discussion. How does this impact the way HRSA proceeds before the MPSC can fully discuss the case and peer visit findings?

The Deputy Director responded that, by being a part of the process, HRSA staff can quickly share preliminary information and coordinate with other entities, such as the Centers for Medicare and Medicaid Services (CMS) and state oversight boards. They are also better able to leverage the Secretary of HHS' authority if a member is uncooperative.

2. .Membership Requirements Revision

OPTN staff provided a status overview of the Membership Requirements Revision (MRR) project and the project goal of performing a comprehensive review of all OPTN Bylaw membership requirements. The *Update Membership Requirements and Application and Review Process** proposal, which proposes changes to appendices A, B, and D of the OPTN Bylaws as part of project phase one, is currently being finalized and is on track to go out to public comment in summer 2024, with OPTN Board of Director (BOD) approval targeted for the December 2024 BOD meeting. Later in the meeting as summarized in item 3 below, the MPSC was informed that HRSA was requesting that the proposal not be released for public comment. The next phase of the project will include a review of the draft framework for transplant program key personnel training and experience requirements previously developed by the Membership Requirements Revision Subcommittee and MPSC.

Staff provided background on the development of the framework, noting that a Request for Feedback on the draft framework went out to public comment in winter of 2021, and that the MRR subcommittee partially reviewed the feedback received before the project was placed on hold. Staff explained that the MPSC review of key personnel requirements was based on issues that have arisen in reviews of applications, feedback received from members completing applications for new programs and key personnel changes, the ability to apply a periodic reassessment of compliance, and a review of state licensing requirements, requirements for various board certifications, fellowship requirements, and past briefing papers supporting existing bylaws. The guiding principles for review include incorporating an element of currency into experience requirements, consolidating multiple training and experience pathways into one pathway that can be met through fellowship experience, clinical experience, or a combination of both, ensuring consistency between all organ-specific training and experience requirements, considering stratification of requirements, and incorporating an option for individuals who trained or gained experience outside of the United States.

Staff reviewed the details of key changes proposed in the framework for both primary surgeon and primary physician requirements, including public comment feedback received and themes from the MRR Subcommittee's discussion of the feedback. Key changes include stratification of requirements for individuals who have previously served in a primary role, the introduction of an OPTN orientation curriculum for those who have not served in a primary role, introduction of a form certifying that an individual meets requirements to replace letters of recommendation, the extension of conditional approval to include the primary surgeon rather than just the primary physician, changes to currency evaluation, and consolidation of pathways. Staff provided a list of requirements retained without modification, noting that most received no or limited feedback during public comment.

Staff highlighted issues for the Committee's discussion, focusing on those that received substantive feedback during public comment or which the MRR subcommittee had not previously reached a consensus. These issues include the determination of alternative language for "on-site" when describing the need for a primary to be physically available to a program, the consolidation of pathways and currency requirements, the exemption from some requirements for individuals who had previously served as primary, the extension of conditional approval to include the primary surgeon rather than just the primary physician, and how to incorporate an option for individuals who trained or gained experience outside of the United States. The Committee formed breakout groups to discuss some of these topics.

Staff concluded by giving an overview of additional items addressed in public comment feedback requiring further consideration, including establishing criteria for surgeons and physicians other than the primary, developing educational materials for key personnel requirements for transplant hospital leadership, and considering minimum requirements for procurement surgeons. Staff solicited additional members for the MRR Subcommittee, noting that several members rolled off the Committee at the end of June. Finally, staff outlined that next steps for the project which include finalizing the primary surgeon and physician framework and reviewing feedback received during summer 2024 public comment on the *Update Membership Requirements and Application and Review Process** proposal before finalizing and submitting it for approval to the Board of Directors at its December 2024 meeting.

Summary of Discussion:

A member asked for background on the history of how primary surgeon and physician requirements and currency guidelines were developed. Staff replied that the Final Rule requires that the OPTN have policies regarding the training and experience of transplant surgeons and transplant physicians and historically, in many instances, fellowship requirements have been used as guidance in development of those requirements. The development of the requirements also involves collaboration with the subject

matter experts on organ-specific committees to determine and modify currency timeframes and appropriate volumes for patients followed, transplant surgeries, and procurements performed for each organ.

Members expressed support for the addition of an OPTN orientation curriculum requirement for individuals who had not previously served as a primary, suggesting that this could be open to those in training. Member comments emphasized the importance of this requirement, noting that it could be leveraged to ensure transplant program personnel are aware of all OPTN obligations.

Members also supported the stratification of requirements for individuals who have previously served as primaries versus those who have not, including exemption from some requirements for individuals who have previously served as a primary within a specified number of years.

Discussion of the primary physician requirement for observation of transplants and procurements resulted in mixed opinions on whether or not observational experience is beneficial to physicians. While some members supported removal of the requirement and some supported its retention, all agreed that more structure is needed around this requirement. A member commented that the required number of observations should be organ-specific to take into consideration organs with lower volumes across the country, such as pancreas. Another member noted that observations are intended to ensure physicians have a holistic understanding of the workings of the transplant system, including transplant hospital and OPO interactions and donor management, and suggested that instead of requiring observation experience, the OPTN orientation curriculum could provide education on these topics, potentially including recordings of procurement and/or transplant procedures. A member commented on the COVID provision allowing for individuals to complete observation experience virtually, and the need to clarify whether virtual observation experience will continue to be accepted.

During discussion of the on-site requirement for primaries, members strongly supported referencing the American Society of Transplantation suggestion to use ""primary location of practice" with minimum commitments to practice of transplant and transplant administration, e.g., 50% for practice of transplant; 10% transplant administration" to replace the term on-site. Members agreed that the intent of the requirement is that primaries must be available at the institution where patients receive care. A member commented that percentage of time could mean different things depending on whether the designated primary is a full-time employee and suggested that requirements specify that percentages are applicable to full time employment hours.

Discussion of potential consolidation of pathways, currency requirements, and previous primary exemptions centered on the need for fine-tuning of the requirements. Members noted the potential effect of volumes on the ability to meet requirements, which could affect access, citing fellowships, hospitals, and/or organ types that by nature have smaller volumes. A member commented on the importance of keeping requirements from becoming too granular and inadvertently preventing qualified individuals from meeting requirements and expressed support for the proposed changes.

During discussion of foreign equivalency to American board certification and/or experience, a member commented that the American Board of Surgeons has recently added a pathway for foreign-trained surgeons to sit for boards if the surgeon has been at same USA institution for at least 5 years. Members questioned whether the requirement for board certification is necessary to demonstrate qualification for primary roles, noting difficulty in assessing foreign equivalency for individuals with training or experience from outside of the United States, and expressing doubt that certification attests to competency. Another member noted that hospitals can require board certification for their surgeons and physicians for billing and insurance purposes. A member suggested that being licensed to practice in a state and credentialed at a hospital is sufficient qualification, noting that staff can practice if they are

licensed through the state, even if they did not train in the United States or Canada and are not board certified. Members commented that the OPTN does not currently re-verify board certification after initial approval unless an individual moves to a different transplant hospital and submits a new application, though this could be an area subject to periodic reassessment once the process is implemented.

While discussing potential changes to conditional approval pathways and extensions of conditional approval to surgeons, members asked how frequently programs request conditional approval due to a sudden departure, and how long programs can remain in conditional approval status. Staff answered that conditional approval requests are infrequent, but sudden departures occur fairly frequently. Conditional approval timeframes are determined on an organ-specific basis, and timeframes fall between one to three years, with variable options for extension of conditional approval status. Members noted the need to better define what constitutes a sudden departure or unanticipated vacancy if the framework will limit conditional approval to situations where there is a sudden vacancy of a primary role.

**See item 3 for the most recent status update for the proposal.*

3. HRSA Remarks Regarding Membership Requirements Revision

HRSA staff provided an update on the Membership Requirements Revision project, first recognizing the work of OPTN staff and Committee members on the *Update Membership Requirements and Application and Review Process* proposal. HRSA staff explained that the OPTN Modernization Initiative has begun and will include a thorough examination of OPTN Membership processes, and so HRSA does not approve the proposal for public comment at this time. Instead, work on the Membership Requirements Revision project will be incorporated into the initiative and will resume when the initiative reaches the point of OPTN Membership process review. The proposal will be considered again at that point, already completed project work will inform initiative work, and the Committee will be engaged when work resumes.

HRSA staff acknowledged that the impetus for this proposal was to complete an OPTN contract task, and that holds on the work have been placed at HRSA's behest.

Summary of Discussion:

The Chair asked about the timeline for the resumption of work on review and revision of the bylaws, noting that for some areas of the bylaws, changes are highly anticipated by OPTN members due to the challenges caused by current requirements. HRSA staff responded that the timeline is dependent on the resolution of awarding of the OPTN contract, which is estimated to be resolved in early 2025.

A member asked for clarification on whether all project work must stop, or if the Membership Requirements Revision subcommittee will continue work even though the current proposal is on hold. HRSA staff confirmed that all project work is on hold.

The immediate past Chair requested further explanation of the rationale for the decision, including clarification on how HRSA staff anticipates that current work would negatively impact future work, and commenting on the possibility of the hold standing for two or more years, the urgency of the changes needed, and the significant amount of Committee time spent on the project. HRSA staff acknowledged the concerns and indicated that more information would be forthcoming.

4. Preparing for Regional Meetings

Staff shared information to prepare Committee members to present on behalf of the Committee at their regional meetings, including meeting logistics for in-person and virtual presenters, recommendations for

best practices for individual preparation, and an overview of the presentation material. The Committee presentation focuses on the *Update Membership Requirements and Application and Review Process** proposal slated for summer 2024 public comment. Additional focused preparation sessions will be scheduled with presenting members after the conclusion of the July in-person Committee meeting. Staff reminded non-presenting members that they are expected to attend at least one regional meeting per year.

**See item 3 for the most recent status update for the proposal.*

5. Performance Monitoring Enhancement Update

Presentation topics included updated transplant program performance monitoring data, the finalized pre-transplant mortality questionnaire to be sent to transplant programs flagged for this metric, data to be included in pre-transplant mortality case packets for reviewers, an overview of and request for additional feedback on the *Update Criteria for Post-Transplant Graft Survival Metrics* proposal public comment document, and a request for additional volunteers for the Performance Monitoring Enhancement (PME) Subcommittee.

Staff reviewed data for transplant programs flagged in July 2024 for all four performance monitoring metrics based on the Scientific Registry of Transplant Recipients (SRTR) MPSC reports. Data break downs included the following:

- number of flags for each organ type for each metric including total number of flags for each metric
- a comparison of adult vs pediatric flags
- number of programs flagged for review by metric and cycle
- number of programs flagged by organ and cycle
- number of programs newly identified over multiple report cycles.

Staff noted that programs that are flagged, undergo review, and are then released are given a one-year grace period before they are required to re-enter MPSC performance review if they continue to be flagged. This operational rule accounts for the fact that MPSC reviewers have likely reviewed the events resulting in the flagging during that year after release because of the time lag in the SRTR metrics.

Staff then gave a brief overview of the pre-transplant mortality questionnaire developed by the Committee and finalized and approved at the June 28, 2024, full Committee meeting. Staff explained that when programs are flagged, they are asked to complete the questionnaire to provide information about the program, its quality efforts, and its plan for improvement.

The Performance Monitoring Enhancement Subcommittee developed recommendations for data to be included in the case review packets for programs flagged for this metric, which included:

- Counts and percentages of waiting list registrations that were active and inactive at a specific point in time
- Distributions of active and inactive waiting time for the candidates who died prior to transplant
- Counts and percentages of offers that were declined by a program but the organ transplanted elsewhere, specifically for registrations that died on the waiting list
- Distributions of offer rates for the candidates

Staff presented a draft data report that included the Subcommittee's recommendations, explaining the methods of analysis used to prepare the data and reviewing the data visualizations in the draft report. The draft report utilized data from a cohort spanning 2021 to 2023, compared the data of the sample transplant program to national and regional averages, and included various breakouts such as organizing data by month, stratification by urgency status or demographic characteristics at time of listing, etc.

Next, staff gave an overview of the *Update Criteria for Post-Transplant Graft Survival Metrics* proposal. The purpose of the proposal is to remove barriers to increasing the number of transplants to support the Expeditious Task Force's bold aim of 60,000 deceased donor transplants in 2026. Committee review of post-transplant graft survival was identified as a potential barrier, based on the perception that the potential for MPSC review of post-transplant graft survival contributes to risk averse behavior by transplant programs. The Committee also considered raising the offer acceptance flagging threshold to capture more programs, thereby creating a stronger incentive for transplant programs to accept more organs.

At its June 28, 2024, meeting, the Committee approved threshold changes for the two post-transplant graft survival metrics of adult 90-day and 1-year conditional on 90-day graft survival rate ratio. The proposed change would revise the threshold from a 50% probability that a transplant program's hazard ratio is greater than 1.75 to greater than 2.25. The proposed threshold changes would only apply to adult transplants; there would be no change to thresholds for pediatric transplants. Staff summarized the Committee's discussion supporting the change including that the new threshold would continue to identify transplant programs that have the most need for improvement, and that the majority of serious patient safety issues are identified through other monitoring activities. In particular, flagging for 90-day graft survival is a more reliable indicator of surgical problems than 1-year conditional, and data showed flag counts only change marginally for the 90-day graft survival metric when comparing a 2.0 threshold to a threshold of 2.25. This rationale will be included in the proposal.

At the June meeting, the Committee also discussed a potential change to offer acceptance flagging criteria, opting not to make changes at this time since the recent implementation of the metric results in a lack of significant experience with reviews under this metric. Reassessment of the need for a change will take place after more review data is available, programs have had more time to become familiar with and start using offer filters, and more robust options have been added to offer filters for all organs.

The proposal is targeted for a special public comment period that will allow for potential Board of Directors approval during its October or November meeting, aiming for implementation of the new thresholds in the January 2025 SRTR MPSC reports. Staff provided data on review of transplant programs flagged for post-transplant outcomes in July 2022, including length of time that programs stayed under review and what actions were taken by the Committee.

Staff requested feedback from the Committee on the rationale for the post-transplant outcome metric threshold change to ensure the reasoning is conveyed accurately and what specific questions should be included in the proposal for public comment. Staff also solicited additional members for the Performance Monitoring Enhancement Subcommittee, noting that several members rolled off the Committee in June.

Summary of Discussion:

While discussing data on the number of flags by metric and cycle, a member asked how this information is being dispersed to the transplant community at large, noting that this particular breakdown of data demonstrates that the risk of flagging is not high, and that it is important to share to help reduce risk-averse behavior caused by concern over being flagged. The member recommended dispersing the information in a Chair email to the community. Staff answered that some of the data covered has been reviewed at regional meetings, but that it is not posted on the OPTN website and affirmed that it could be added to the resources already available in the toolkit and included in a Chair email to the community.

A member noted that both adult and pediatric heart programs are disproportionately flagging on pre-transplant mortality, soliciting potential solutions. Staff recommended consulting with the Heart

Transplantation Committee if needed after the Committee has started reviewing programs flagged for this metric. After the Committee has conducted reviews and has a clearer picture of flagged program operations, it may become apparent why this is the case. One potential option could be recommending collection of additional data elements for use in the risk adjustment models identified by the Committee during reviews.

During review of the draft report for data to be included in pre-transplant mortality review packets, members asked clarifying questions about the data, such as percentages of programs flagged and total number of programs under review and made recommendations for adjustments to data breakdowns and figures.

While discussing the *Update Criteria for Post-Transplant Graft Survival Metrics* proposal, members supported the summary of the rationale described by staff for the change in post-transplant outcome thresholds and reaffirmed the Committee's decision to hold off on changes to offer acceptance criteria until more data is available. For specific questions to be included in the proposal for public comment, the Committee supported the inclusion of the recommended questions. In addition, a member suggested adding a question directed at the pediatric community about whether they support a threshold change for pediatric transplants. The Committee Chair noted that the rationale for excluding pediatric programs from the threshold change is the small number of programs and small percentage of programs flagged, and cautioned the Committee about making changes that impact this vulnerable population.

Another member commented on the lack of research on transplant program behavior, noting that they participated in a study on this topic that is still in review and not yet available, and emphasizing the need for better understanding of physician behavior to inform these efforts.

The OPO Performance Monitoring Enhancement Workgroup Chair recommended setting up a Workgroup meeting to provide members with information on the OPO metrics developed by the SRTR. Staff noted that at another point in the meeting, additional Workgroup members will be solicited to re-populate the workgroup as some members rolled off the workgroup in June. Upcoming Workgroup meeting agenda items will include contributing to the OPTN public comment response to the 60-day Federal Register notice once it is posted. The SRTR described the OPO metrics they had developed and indicated a willingness to provide information on these metrics to the Workgroup if HRSA agrees. Work on these metrics has been paused at the request of HRSA.

6. Continuous Distribution Update

OPTN Contractor staff presented an overview and update on continuous distribution. Continuous distribution is a points-based allocation system that considers multiple attributes simultaneously to determine the order of allocation. In March 2023, the OPTN implemented continuous distribution of lungs. Presently, the other organ-specific OPTN committees are working on continuous distribution and will have update papers out for review during the upcoming public comment cycle.

Summary of discussion:

A member noted the low weight that was placed on the placement efficiency attribute through the kidney values prioritization exercise, while emphasizing that placement efficiency is key to addressing the nonuse of kidneys. The presenter responded that the values prioritization exercise provides the committees with a starting point for considering weights for each attribute, but through optimization exercises with the Massachusetts Institute of Technology (MIT) the committees are able to understand the impact of those attribute weights and refine them. A member added that in order to make the system more efficient, there needs to be a greater emphasis on placement efficiency through weighting

and including more attributes within the placement efficiency goal. The presenter commented that when the OPTN Lung Transplantation Committee developed their continuous distribution framework, they opted to include a smaller number of efficiency attributes and as the community has learned and faced other challenges, they are looking for ways to add more attributes into that goal.

A member inquired what is meant by the Patient Access goal. The presenter clarified that the Final Rule requires policies be developed in support of patient access. For lung continuous distribution, pediatric patients and prior living donors were attributes identified under this goal. The other organ-specific committees are planning to utilize these two attributes as well, with the OPTN Liver and Intestinal Organ Transplantation Committee also considering how to integrate population density into the Patient Access goal. A member noted that multi-organ transplants are not listed as an attribute, to which the presenter responded that it would likely be included under the Patient Access goal in a future iteration of continuous distribution. The member added that highly sensitized, pediatric, or prior living donor kidney alone candidates can often by surpassed by candidates who need a multi-organ transplant.

A member inquired if there had been any thought to the way that population density was correlated between both Patient Access and Placement Efficiency and how that may look different in various parts of the country or based on donor characteristics. The presenter responded that those discussions are definitely happening within the OPTN and, ultimately, the OPTN Board of Directors will decide on how heavily they want Placement Efficiency to be weighted and what will be integrated into that goal. A member inquired if allocation out of sequence would be taken into consideration as a factor potentially negatively impacting Patient Access. The presenter noted that this push and pull between attributes and goals highlights the ethical challenge in placing utility and equity, but these conversations continue to be prioritized by the organ-specific committees and the OPTN Expeditious Task Force.

A member asked why post-transplant survival is not included in each system's continuous distribution framework. The presenter clarified that the Lung Committee had a post-transplant survival score that had been used for years and was able to be integrated into their framework. Alternatively, the Liver Committee did not feel there was a scientifically sound model to use for liver patients and opted to exclude it from the values prioritization exercise. After receiving some negative feedback on that decision, the Heart Committee opted to include post-transplant survival in their values prioritization exercise despite making the same decision that there was not a scientifically sound model to use. The Heart Committee was still interested in seeing how the community prioritized this goal despite not intending to integrate it in their first iteration of continuous distribution. A member provided greater historical context to how the treatment of heart candidates prior to transplant was a bigger focus of the heart community and allowed for the development of additional measures of earlier support in lieu of dedicating focus to longer term survival models.

7. Expeditious Task Force (ETF) Updates and Progress

The MPSC representative on the Expeditious Task Force (ETF) provided an update on various initiatives and projects aimed at improving organ transplantation efficiency and effectiveness. The Task Force worked to set a Bold Aim and aims to achieve 60,000 successful deceased donor organ transplants annually by 2026, focusing on growth and efficiency while maintaining safety and equity. There are two videos available on the OPTN website explaining setting of the bold aim and the importance of the community taking action now. He then introduced and updated other major initiatives of the ETF:

- Rescue Pathways: The Task Force is testing multiple organ allocation protocols under a policy variance. The Executive Committee has approved the first protocol to be tested, "Pre-cross-clamp placement of Kidney Donor Profile Index (KDPI) 75-100 kidneys," to improve organ placement and reduce cold ischemic time. The protocol is set to begin later this month with

voluntary participants are selected by the ETF Rescue Pathways Workgroup from interested OPOs and kidney transplant programs. The protocol allows placement earlier in the organ offer process of deceased donor kidneys with a Kidney Donor Profile Index (KDPI) of 75 percent or higher, after high priority classifications are made.

- Late Decline Discovery Project: This project investigates the factors behind late declines in organ acceptance, with the goal of standardizing definitions and identifying improvement opportunities. The Late Declines Workgroup collected qualitative feedback from 12 OPOs in May where organ placement was affected by situations such as a late decline of an organ offer, surgical damage to the organ, disrupted transportation, or similar unanticipated challenges. The most common impact of these cases was re-allocation of the organ offer, which happened 48 percent of the time. The next most common effects were organ non-use (18 percent), an open offer (11 percent), or an increase in organ preservation time (7 percent). The workgroup will continue to develop opportunities to:
    - Better define a late decline and understand how it varies in practice
    - Identify and share effective practices to reduce or mitigate late declines
    - Collaborate with OPTN committees to develop policies or projects to address the issue
    - Develop and adapt a study model that can be used to inform other, similar quality improvement initiatives
- Non-use Initiatives: The task force is analyzing data to understand why some organs go unused, focusing on donor characteristics, offer acceptance patterns, and qualitative research in four areas:

    Pillar 1: Donor/Organ Clinical Characteristics – Ongoing development of a potential non-use metrics dashboard to better quantify the clinical factors associated with non-use and establish a baseline for future comparison

    Pillar 2: Offer Acceptance Patterns – Studying new transplant program-specific recommendations to apply to the Offer Filters models

    Pillar 3: Expert Simulation Evaluation Panel – Designing a study to understand the degree to which cold ischemic time affects whether recently non-used kidneys may be considered transplantable

    Pillar 4: Qualitative/Attitudinal Research – Currently holding recurring conversations with representatives of 15 OPOs to investigate reasons for non-use not captured in OPTN data and factors that drive organ non-use
- Transplant Growth Collaboration (TGC) Events: These events are designed to share successful practices in organ transplantation and motivate the community. Several regional events have been conducted, with more planned.
- Other Focus Areas: The task force is also working on removing barriers to transplant through policy analysis, improving patient education, standardizing donor information, refining offer filters, and hosting quality improvement forums.

In all key initiatives the Task Force emphasizes an iterative approach to testing and improving, with a strong focus on collaboration, feedback, and data-driven decision-making.

8. Network Operations Oversight Committee (NOOC) - General Update

OPTN staff provided information on the *Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements* proposal's impact on the Committee. The proposal is sponsored by the NOOC and has been implemented in phases since its approval by the Board of Directors in June of 2023. The proposal overhauls information security requirements for OPTN members.

The current phase of implementation focuses on OPTN Policy 3.1.A (*Security Requirements for Systems Accessing the OPTN Computer System*), which requires OPTN members to attest to their adherence to the new information security requirements for systems accessing the OPTN computer system. OPTN members are assigned to one of three waves with staggered deadlines for attestation submission, with deadlines for the first wave having passed, and the deadline for the second wave coming up on July 31, 2024. The NOOC is overseeing the implementation process and review of member submissions; OPTN staff has managed logistics for communication of deadlines and member submission of attestations.

As the only OPTN committee that conducts peer review and that can potentially take action against members, the MPSC may receive referrals from the NOOC to conduct review of members who fail to comply with the new requirements. OPTN staff asked Committee members to consider what information would be helpful for inclusion in review packets should the need for review arise, suggesting a list of items the member has not completed and frequency of OPTN staff engagement, particularly when giving notice of deadlines and requirements, as starting points. Staff also asked whether the Committee would support closing cases without Committee review if OPTN members became compliant while working with staff after NOOC referral.

Staff will share information on potential referrals as it becomes available, and should any referrals come out of the August NOOC meeting, will target the September Committee meeting for review.

Summary of Discussion:

A member commented that the new requirements are straightforward, and that OPTN members who do not comply should not have access to the OPTN computer system. Staff clarified that Committee review could result in the regular actions specified in the bylaws that reviewers typically consider, such as a notice of noncompliance, and that consideration of revocation of OPTN member access to the OPTN computer system will go through a different process managed by another group.

The Committee supported inclusion of a list of items the member has not completed and frequency of OPTN staff engagement in review packets, as well as closing cases without Committee review if referred members become compliant while working with staff.

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

OPTN staff updated the Committee on the MPSC's current policy, education, and communication efforts. The purpose of the discussion was for Committee members to review and discuss each ongoing initiative, and to provide feedback on suggested or proposed new policy changes, educational efforts, programming improvements, or community communication. Staff discussed each ongoing effort and the MPSC had questions and offered feedback.

Recommendations for Policy Improvements

Staff outlined the process for the MPSC to recommend a policy change through a referral to the Policy Oversight Committee (POC) and to the appropriate OPTN policy-making committee. Prior to the formalized policy referral process, the MPSC would send informal recommendations to the Committees for suggested work. Reasons that the MPSC may recommend a policy change include when the MPSC

finds that a policy is no longer applicable, lacks necessary elements based on changes in practice, confuses members, is difficult to monitor or enforce, or can be improved to address known safety or efficiency concerns.

MPSC Policy Referrals – *Implemented*

Staff updated the Committee on referrals that were developed into policy proposals and have been implemented:

- 2022 recommendation to the OPO Committee to address late turndowns and non-utilization due to duplicate acceptances
    - The proposal *Modify Organ Acceptance Limit* was approved by the OPTN Board of Directors on December 4, 2023, and implemented on May 28, 2024.
- March 2023 referral to the Ad Hoc Disease Transmission Advisory Committee (DTAC) to revise patient safety policy
    - The proposal *Standardize the Patient Safety Contact and Reduce Duplicate Reporting* was approved by the OPTN Board of Directors on June 17, 2024, and the requirement for a secondary patient safety contact was implemented July 25, 2024. The remaining implementation, including technical updates and the auditing component, will occur in spring 2025.
- March 2023 referral to the OPO Committee to clarify DCD conflict of interest in policies in declaration of death
    - The proposal *Clarify Requirements for Pronouncement of Death* was approved by the OPTN Board of Directors on June 17, 2024, and was implemented on July 25, 2024.

MPSC Policy Referrals – *In Progress*

Staff updated the Committee on referrals that are currently in development:

- March 2023 referral to the DTAC to revise the requirements for communicating post-transplant diseases
    - The DTAC is currently working on this project and anticipating a two-phase approach, with the first phase slated for Winter 2025 public comment.
- July 2023 referral to the Operations and Safety Committee (OSC) to add a pre- and post-transfusion data label
    - The OSC is looking to incorporate this into their *Re-evaluation of Deceased Donor Testing Requirements* project, which is slated for Winter 2025 public comment cycle.
- November 2023 referral to the OPO Committee to specify procurement team responsibilities
    - This project is slated behind the OPO's current work on machine perfusion data collection.
- March 2024 referral to the Minority Affairs Committee (MAC) and Kidney Transplantation Committee to specify requirements for eGFR review
    - The MAC began work on this project in June 2024 and is receiving support from members of the MPSC, Kidney, Transplant Administrators, and Transplant Coordinators Committees. This project is tentatively slated for Winter 2025 public comment cycle.

MPSC Policy Referrals – *Work Pending More Information*

These referrals have been well received by the respective OPTN Committees they were sent to, and the Committees intend to take up work on them. However, they are waiting for more information from the Expeditious Task Force's *Late Declines Discovery Project* to better understand the issues and inform the next steps. These referrals are:

- December 2023 joint referral on transportation data collection sent to OSC and the Data Advisory Committee (DAC)
    - This referral will be led by the OSC with support from members of the DAC.
- March 2024 referral sent to the OPO Committee to address late declines
- March 2024 referral sent to OSC to address organ chain of custody issues

MPSC Policy Referrals – *On Hold*

Staff updated the Committee on MPSC referrals that are currently on hold and do not have plans for progressing at this time:

- 2022 recommendation to the DTAC to clarify HIV results
    - The DTAC developed a concept paper *Clarification of OPO Requirements for Deceased Organ Donors with IV Positive Test Results Concept Paper*, however, the DTAC did not receive the amount of information they needed.
- March 2023 referral to DTAC to review prohibited vessel storage policies
    - The OPTN is unable to modify its HCV+ vessel storage policies without modification to the U.S. Public Health Service (PHS) Guideline permitting the storage of these vessels, and the Centers for Disease Control and Prevention (CDC) has indicated they are not supportive of modifying for this purpose.
- March 2023 referral to OSC to create a centralized vessel storage and tracking mechanism
    - The OSC proposed developing a concept paper to gather information from the community on the issues they are experiencing related to vessels. While the Policy Oversight Committee (POC) recommended approval, the Executive Committee declined further work on this project in February 2024.

Potential New MPSC Policy Referrals

- Normothermic Regional Perfusion

Based on conversations earlier in the week, the MPSC had indicated an interest in sending a policy referral on normothermic regional perfusion (NRP). Staff highlighted that OPTN Policy 2.14 (*Organ Procurement* and 2.15 *Requirements for Controlled Donation after Circulatory Death (DCD) Protocols* are the only policies related to NRP. The OPO Committee has a proposal *Enhancements to OPTN Donor Data and Matching System Clinical Data Collection)* to collect basic NRP-related data, which has been approved by the OPTN Board of Directors but is pending approval by the Office and Management and Budget (OMB) in order to be implemented. The MPSC was asked to refine what the issue requiring a policy solution is and which OPTN Committee this should be referred to.

Summary of Discussion:

A member noted the unpredictability in practice due to the variable number of teams who are participating in the procurement. A member noted that despite the proposal pending implementation, the field and practice of NRP has evolved prolifically since approval by the OPTN Board of Directors and more granular data as well as guardrails in policy are needed. The member also recommended referring the project to the OSC over the OPO Committee. Another member recommended expanding data collection for all machine perfusion techniques, beyond just NRP, and how the identification of a specific recovery method could impact other organs and their procurement teams.

Another member noted that the third-party involvement in procurement adds another level of complication and policy needs to set clear expectations on roles and responsibilities to ensure safety and compliance. Another member added that there should be some clear communication or checklist

prior to leaving for procurements that outlines exactly what is needed and expected by each member engaged in the process. Members highlighted the vast diversity in NRP protocols between each OPO and the need to promote stability and consistency in practice. A member also noted the potential risk engaging third parties to perform NRP on behalf of an OPTN member and the challenge associated with being responsible for the vendors actions in a highly variable and complex environment.

A member added that current policy has certain requirements host OPOs must comply with related to labeling but that there are roadblocks in meeting these requirements based on the machine type. Members also noted that they did not want to hinder the development of future technologies, and perhaps guidelines or standards would allow flexibility and innovation. A member noted that too stringent policy requirements could have potentially unintended consequences.

In terms of the next steps, OPTN staff will collate this feedback and identify ways in which some of this feedback could be integrated into other work. Currently, the OPO Committee is looking at developing a data collection proposal on machine perfusion and the OSC is reviewing the deceased donor required testing policies. Both projects may have the potential to address some of the feedback discussed. MPSC leadership will then review the remaining feedback from the Committee and determine if there is a more refined and distinct referral that could be made to another OPTN Committee.

Third Party Vendors

Members were asked if any other issues had been discussed during the week that required a potential policy solution to address. They are interested in discussing and referring a project related to Third Party Vendors.

Summary of Discussion:

A member expressed their surprise when informed that no vendors had been reported to the Food and Drug Administration (FDA) based on the extent of the discussion within the community. It appears as if this information is underreported to both the FDA and to the OPTN which may require further community education, with specific focus to the responsibility of OPTN members in reporting third parties to the OPTN Patient Safety Reporting Portal. Members expressed a shared experience where third-party vendors requested access to information that seemed far beyond what they needed to effectively complete the contracted tasks.

A member mentioned the potential role of integrating third parties into the OPTN but did not want them to have the rights and privileges of serving as full OPTN members with voting privileges and committee membership. Members noted that as a community they are unaware of the scope of the problem and the quantity and quality of the issues that are occurring. The Committee agreed to work on education through the Chair emails and a member recommended developing an MPSC subcommittee to discuss the issues at greater length.

A HRSA representative noted that the OPTN is not able to report incidences directly to the FDA, but the OPTN and MPSC should encourage those who experience these issues to report them directly to the FDA. The HRSA representative said that the MPSC can track these incidences separately from the FDA, but they need to be reported by members to both regulatory bodies. A member recommended collecting information on device/product malfunctions as well as provider issues. A member noted that hospitals are collecting this information individually, but it is not housed in an aggregate format.

A member suggested bringing together a group of transplant administrators and OPO representatives to discuss best practices around vendor engagement for after-action quality review processes. The MPSC has learned of some instances where things have gone well in quality review and training between members and their vendors, so it would be beneficial to the community at large to share that

knowledge. In terms of next steps, the responsibility and necessity of reporting third party vendor incidences will be included in the Chair email as a continued attempt to educate the community on reporting.

Email Communications

Staff summarized past Chair topics and highlighted potential topics that have been identified throughout the Committee's discussions during the meeting. The Committee agreed on the following email topics:

- Organ verification
- Performance metric flagging
- Network security requirements
- Reporting third party vendors to the OPTN Patient Safety Reporting Portal and FDA, when applicable

10. Report of Investigative Activities

OPTN Contractor staff supplied a summary of investigative activity from June 2024 and a rolling four-month report from March 2024 through June 2024. The reports 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. Classification variances over the quarter were presented and no significant trending outliers in non-compliance were identified. Committee members asked questions related to third party vendor involvement in patient safety reports. The OPTN Contractor staff reported that the OPTN contractor received 17 reports in the last year that mentioned third party vendors, but this does not imply they were at fault. The Committee further discussed setting pathways for continued monitoring of these types of events, but a final resolution was not determined.

11. 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 33 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 the December 2024 meeting.

- Approve 2 new transplant programs
- Approve 1 new public organization membership
- Approve 1 business membership renewal

The Committee reviewed and approved the following personnel changes.

- 4 applications for new key personnel for Transplant Programs or Components
- 17 applications for changes in key personnel for Transplant Programs or Components
- 3 applications for changes in key personnel for Histocompatibility Laboratories

The Committee reviewed and approved 2 applications for geographic requirements for Transplant Programs or Components

In addition, the Committee discussed two applications that were not on the consent agenda.

12. 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 21 transplant programs: two heart programs for 90-day graft survival, and two heart programs for 1-year conditional graft survival; four kidney programs for 90-day, three kidney programs for 1-year conditional; three liver programs for 90-day; four lung programs for 90-day, and one lung program for 1-year conditional; and two pancreas programs for 90-day. Additionally, the Committee approved the release of monitoring of nine transplant programs: three heart programs for 90-day graft survival, three heart programs for 1-year conditional; two liver programs for 90-day graft survival, and one liver program for 1-year conditional.

For transplant programs under review for offer acceptance, the Committee approved the continued monitoring of 14 transplant programs: seven kidney programs, five liver programs, and two lung programs. Additionally, the Committee approved the release of monitoring of 22 transplant programs: six heart programs, five kidney programs, seven liver programs, three lung programs, and one pancreas program.

For transplant programs under review for functional inactivity, the Committee approved the continued monitoring of one lung program and one pancreas program. Additionally, the Committee approved the release of monitoring of one kidney program, one heart program, and one pancreas program.

The Committee approved the consent agenda by a vote of 31 For, 0 Against, and 1 Abstention. The Committee also discussed the details of 9 cases during the closed session.

13. Compliance Issues

The Committee reviewed a consent agenda consisting of 28 transplant programs that had undergone a focused desk review during this cycle, including three heart programs, 10 kidney programs, three living donor kidney components, five liver programs, four lung programs and three pancreas programs. The Committee released 17 of those programs from monitoring and 11 program reviews were recommended for follow-up focused desk reviews. The Committee also reviewed 19 OPOs and one transplant program for allocation errors, all of which were closed with no action. The Committee reviewed 55 case investigations this cycle, consisting of member complaints or self-reported potential policy violations. The Committee issued 34 Notices of Noncompliance and closed 21 issues with no action, 13 of which were closed for self-reporting. In addition, the Committee reviewed 17 reported living donor events. Nine events were aborted procedures, including five aborted nephrectomies and four aborted hepatectomies, all of which were reported within required timeframes and closed with no action. There were six living donor redirections; four events were reported on time and closed with no action and two Notices of Noncompliance were issued for late reporting. Two cases involved deaths of living donors within two years of donation; one involved a motor vehicle accident and the other involved development of glioblastoma. Both cases were reported on time and were closed with no action.

The Committee approved the consent agenda by a vote of 35 Yes, 0 No, and 1 Abstention. The Committee also discussed several ongoing cases.

14. Estimated glomerular rate (eGFR) Case 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. As of January 4, 2024, all kidney programs have submitted an attestation that the policy requirements were met. HRSA raised concerns and requested that the Executive Committee discuss potential further action for members who

submitted an attestation but did not submit (or submitted few) modifications while having Black/African American candidates on their lists.

The MPSC discussed how to address members who submitted attestations but had few modifications and decided to send an inquiry to programs in the lower 25th percentile, who submitted modifications for fewer than 20% of their patients listed as Black/African American. Programs identified by this data review were asked to provide a template of notifications with dates, the process for evaluating eligible patients, the time and effort required for the policy implementation, the evaluation process for dialysis patients, and an explanation for the low number of modifications.

After the 30-day deadline, 56 members received inquiries. During the MPSC's March 29 meeting the committee reviewed the programs' responses and determined that 45 program reviews could be closed with no action and 11 programs required additional information.

The 11 programs provided clarification or information about re-reviewing their waitlisted patients for eligibility. Subcommittee reviewers agreed that six out of the 11 program reviews could close with no further action. The MPSC approved the consent agenda 32 yes, 0 no, and 0 abstentions.

Upcoming Meetings

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

Attendance

- **Committee Members**
  - Kamyar Afshar*
  - 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
  - Deborah McRann
  - Clifford Miles
  - Saeed Mohammad
  - Lloyd Ratner
  - Deirdre Sawinski
  - Malay Shah
  - Nirmal Sharma*
  - Zoe Stewart Lewis
  - Carrie Thiessen
  - James Yun*
- **HRSA Representatives**
  - James Bowman*
  - Shannon Dunne*
  - Frank Holloman
  - Marilyn Levi*
  - Arjun Naik*
  - Kala Rochelle*

- **SRTR Staff**
  - Jonathan Miller*
  - Jon Snyder
  - Bryn Thompson*
- **UNOS Staff**
  - Anne Ailor*
  - Robert Albertson*
  - Stephanie Anderson
  - Sally Aungier
  - Tameka Bland*
  - Torry Boffo*
  - Tyrone Brown*
  - Jadia Bruckner*
  - Elinor Carmona*
  - Robyn DiSalvo
  - 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*
  - Jon McCue*
  - Amy Minkler*
  - Heather Neil*
  - Jacqui O'Keefe
  - Rob Patterson
  - Emily Powell*
  - Shawn Richman*
  - Melissa Santos*
  - Laura Schmitt
  - Erin Schnellinger*
  - Sharon Shepherd
  - Courtney Skeen*
  - Sarah Stevenson*
  - Stephon Thelwell
  - Melissa Tisdale*
  - Emy Trende
  - Marta Waris
  - Betsy Warnick
  - Trevi Wilson*

- Claudia Woisard*
- Hobie Wood*
- Hollie Woodcock*
- Karen Wooten*
- Carson Yost
- Amanda Young*

- **Other Attendees**
  - None

** Participated virtually*