OPTN Membership and Professional Standards Committee
Meeting Summary
March 4-6, 2025
Conference Call

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Introduction

Membership and Professional Standards Committee (MPSC) met virtually in closed and open session on March 4-6, 2025, to discuss the following agenda items:

1. Clarify Requirements for Reporting a Potential Disease Transmission
2. Establish Comprehensive Multi-Organ Allocation Policy
3. Multi-organ Post-Transplant Graft Survival
4. Upcoming Business Member Application Updates
5. OPO Committee Presentation on Machine Perfusion Data Collection
6. Require Reporting of Patient Safety Events - 2nd Post-Implementation Monitoring Report
7. SRTR: Kidney/Pancreas Pre-transplant Mortality Evaluations
8. Performance Monitoring Enhancement
9. MPSC Education/communication Initiatives and Policy Referrals
10. Third Party Issues
11. Performance Issues
12. Compliance Issues
13. Membership Issues

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

1. Clarify Requirements for Reporting a Potential Disease Transmission

No decisions were made

OPTN contractor support staff for the Ad Hoc Disease Transmission Advisory Committee (DTAC) presented the Committee's proposal *Clarify Requirements for Reporting a Potential Disease Transmission*, which is currently out for public comment. The proposal was developed following a referral from the MPSC to define an unexpected potential donor-derived disease transmission event (PDDTE) and to clarify lung reporting requirements. The proposal defines an unexpected PDDTE as a pathogen, disease, or malignancy not known in the donor at the time of cross-clamp. It also defines a sick lung recipient as a lung recipient with an organism isolated from the respiratory tract or other site that directly contributes to the lung recipient's illness based on the clinical judgement of the treating physician or team. All other lungs not meeting these criteria are considered non-sick lung, and only organisms on the Pathogens of Special Interest list should be reported for non-sick lung recipients.

Summary of discussion:

A committee member began by asking for clarity about the timeline for a sick lung recipient to be considered a donor derived illness and staff noted that the DTAC was hesitant to put a timeframe on

that given the various development periods of malignancies or other fungal organisms. The DTAC wanted to allow flexibility to rely on clinical judgement, but they are also working on updating guidance documentation to aid programs in this determination. The MPSC member noted that the DTAC should consider reviewing data on outcome differences for expected vs. unexpected PDDTEs and for sick lung recipients versus non-sick lung recipients given the implications of factors not known at the time of acceptance or cross clamp.

There was some confusion from members regarding the use of donor cross clamp or recipient cross clamp for the definition of unexpected, and staff clarified that the proposal is for donor cross clamp. Staff added that the DTAC did consider other time frames such as the time of acceptance but there were issues with consistent data collection and delays between acceptance and transplant time. Several members noted that particularly in kidney allocation, there could be an extended period between the cross clamp and transplant, and it would be possible for testing to result in that window that should then be considered expected. From a compliance standpoint, this could create a burden for members and the committee for events to be submitted and reviewed as unexpected even when the results were known prior to the acceptance or transplant.

A member inquired if the DTAC would consider a different terminology than sick or non-sick lung recipient so that it is less ambiguous about its meaning, and staff responded that it is under consideration as there has been other similar feedback during other OPTN committee presentations and that any suggestions are welcome. The member also asked if the lung recipient illness is always so dichotomous and how the policy could address any potential ambiguity between the two options.

A member suggested utilizing differing definitions of the start time for different organs when outlining expected versus unexpected, which would help bridge the gap between something like a lung offer where acceptance is usually well before cross clamp, and something like a kidney offer where acceptance could be well after cross clamp. It was also suggested that it would be important to address areas of ambiguity in sick versus non-sick lung recipients because members see bronchiole cultures showing the same organism seen in donors, but there is a grey area in calling that a pathogen or just colonization. In terms of compliance, it is important to have clarity about when reporting is required or not. The Chair suggested using donor cross clamp for heart, lung, and liver cases and recipient cross clamp for kidney cases in terms of the expected or unexpected definitions.

Another member discussed limiting the definition of sick versus non-sick lung recipients to just organisms isolated from the respiratory tract and not include any “other sites” as noted in the proposal. There was concern that with other sites there is a large amount of ambiguity about certain pathogens that may not fall onto the Pathogens of Special Interest list but still contribute to a recipient’s illness, and that including those sites in the non-sick definition could lead to possible underreporting.

Finally, the Chair noted that the language of the proposed policy is very similar, particularly in the subsection titles, which leads to some possible confusion regarding content and requirements and that taking another look at clarifying that could be beneficial to the community.

2. Establish Comprehensive Multi-Organ Allocation Policy

No decisions were made

The Co-Chair of the Ad Hoc Multi-Organ Transplantation Committee, Dr. Zoe Stewart-Lewis, presented the Committee’s request for feedback *Establish Comprehensive Multi-Organ Allocation Policy*, which is currently out for public comment. Members were asked to provide feedback on the work done to date to inform the upcoming policy proposal. The MOT Committee’s upcoming policy proposal provides an

opportunity to establish policies directing the match runs from which multi-organ offers can be made. The MOT Committee aims to have a final policy proposal out for review during the Summer 2025 public comment cycle.

Summary of discussion:

MPSC members consistently praised the accomplishments of the MOT Committee in tackling this complex problem and creating a workable solution. A member asked about the work done to identify the two appropriate lung composite allocation score (CAS) thresholds to allocate from, and the percentage of lungs allocated above and below those CAS. The presenter highlighted the work done by the lung multi-organ workgroup to identify the appropriate cut off around the 90th percentile. A member commented that a current flaw in the CAS is that a higher creatinine value leads to a lower CAS, which affects how holistically the CAS reflects the medical urgency of the candidate.

A member inquired how the MOT Committee envisions this framework adjusting as allocation evolves and more organs transition to a continuous distribution system. The presenter responded that multi-organ allocation tables would no longer be relevant when all organs have transitioned to continuous distribution frameworks, however the timeline for the completion and implementation of these allocation changes is currently unknown and creating an inconsistency in practice. The presenter also noted the potential for confusion and inconsistency in allocating to multi-organ candidates as a potential cause for allocation out of sequence (AOOS), which the transplant community continues to grapple with.

A member commented that OPOs may still experience some logistical challenges upon implementation since the policy will not be programmed in a way where the OPTN Computer System independently drives the allocation process and could still rely on OPO discretion. A member inquired if the MOT Committee considered implementing this work through a dynamic match run that allowed multiple match runs to communicate with each other and updated to reflect the next required offer as organs are allocated. A member inquired if there could be instances where two kidneys are available, and both are required to be shared for a simultaneous heart-kidney (SHK) and a simultaneous liver-kidney (SLK) over a kidney-pancreas (KP) combination. The member noted there is a potential that this could penalize an OPO because they are being assessed on the utilization of organs available for procurement and transplanted and the OPO is unlikely to allocate the pancreas in isolation. The presenter elaborated on the example multi-organ allocation table highlighting that there are a multitude of potential combinations that could be allocated to before a KP candidate is the required share.

A member wondered about the MOT Committee's consideration of addressing instances of reallocation and how that impacts the next required shares on the match run. The presenter emphasized that this work does not change existing allocation policies related to reallocation and the effect of an offer acceptance on remaining allocation requirements. Members discussed how communication plays a role in these instances and a member recommended the functionality for the transplant program to see the match runs the OPOs are allocating from in order for the transplant programs to understand that their multi-organ recipient may be bypassed if one of the organs has been accepted by a single organ candidate higher on the priority list.

Since the data to inform the multi-organ allocation priority integrates data from 96% of donors, a member questioned if the MOT Committee considered not permitting multi-organ allocation from the remaining 4% of donors in an effort to improve system efficiency. The presenter noted that while there are fewer multi-organ combinations from those donors, there are still some SLK transplants occurring with variability based on center acceptance practices and patient needs. The presenter noted that while

less frequent, it would remain beneficial for those organs to still have the opportunity to be allocated to a multi-organ candidate if the accepting center felt they were a good fit.

A member inquired about the plan to evaluate this proposal post-implementation to monitor for potential adverse effects or unintended consequences, noting specific concern for pediatric candidates. The presenter emphasized that the MOT Committee is not changing current allocation but instead building a framework for OPOs to allocate to multi and single organ candidates in a consistent manner based on medical urgency. The presenter added that all OPTN policy proposals, especially those related to allocation, will have rigorous post-implementation monitoring and review process.

3. Multi-organ Post-Transplant Graft Survival

The MPSC does not currently evaluate graft survival for transplant program multi-organ transplants. OPTN contractor staff provided an overview of previous MPSC work to establish review processes for transplant program performance on multi-organ transplants in 2014-2015. An MPSC workgroup reviewed SRTR data analyses provided of multi-organ transplant volumes and outcomes and the options that were available for the MPSC to analyze the outcomes of multi-organ transplants. Following review of those analyses, the workgroup recommended that the MPSC initially review only simultaneous liver kidney (SLK) transplant outcomes using separate models for SLK and single organ transplants and recommended that a SLK pilot evaluation be done prior to consideration of how to move forward with full implementation. At that time, the MPSC suspended work on this project and has not returned to it because a number of projects were established to evaluate broader changes to the MPSC's transplant program performance review process. OPTN contractor staff have provided data on the annual volumes of multi-organ transplants in the last three years. Multi-organ transplant types with less than 10 transplants annually were not included.

SRTR staff provided an overview of data provided to the MPSC workgroup in 2014 and 2015 and the decisions made by the workgroup and the current state of SRTR reporting of multi-organ transplant outcomes. Data was presented that compared current to the 2014 volumes of different types of multi-organ transplants. SRTR staff then reviewed the questions that would need to be answered by the Committee to incorporate multi-organ transplant outcomes in the SRTR reports to the MPSC:

- Which types of multi-organ transplants to evaluate?
- Which program will be held accountable?
- Whether to evaluate multi-organ recipients separately from single-organ recipients?
- How to represent graft failure – each organ separately or either organ?

Summary of discussion:

Decision #1: The Committee supported beginning work on a Multi-organ Post-Transplant Graft Survival project by a vote of 30 For, 1 Against, 1 Abstention.

Decision #2: The Committee supported the formation of a workgroup that would include representatives from organ-specific committees.

Decision #1: The Committee supported beginning work on a Multi-organ Post-Transplant Graft Survival project by a vote of 30 For, 1 Against, 1 Abstention.

Committee members supported the development of a process to review multi-organ transplant outcomes noting that there is a significant volume of certain types of multi-organ transplants and there does not appear to be any justification for the exclusion of multi-organ transplants from MPSC post-

transplant graft survival performance monitoring. Members also noted that it is important that the MPSC evaluate multi-organ transplant outcomes because the lack of review of multi-organ transplant outcomes likely leads to a greater risk of futile transplants using organs that could otherwise be available to patients in need of single organ transplants.

Decision #2: The Committee supported the formation of a workgroup that would include representatives from organ-specific committees.

Committee members supported the establishment of a workgroup that would include representatives from organ-specific committees. The Committee discussed potentially inviting organ-specific committee representatives based on the multi-organ type to be discussed at each individual meeting.

4. Upcoming Business Member Application Updates

OPTN staff provided an update to the MPSC regarding the pending implementation of the Network Operations Oversight Committee's (NOOC) project, *Revise Conditions for Access to the OPTN Computer System*. There are changes to the business member application process that were highlighted for the Committee for awareness during their reviews for the upcoming 90-day application window post-implementation. Around twenty-five businesses are expected to apply for membership and all new requirements will be communicated to those organizations by the OPTN contractor, as well as included in the staff summaries for MPSC review.

Summary of discussion:

Several committee members highlighted the potential for some research-based organizations not to meet the new requirements for access and the potential for disruption of their current processes. A member asked how the access to the OPTN Computer System is going to be granted or revoked, and staff clarified that it will be the responsibility of OPTN members to monitor and audit individuals and organizations that they grant access to.

5. OPO Committee Presentation on Machine Perfusion Data Collection

The Chair of the OPO Committee presented on the progress to date of the Machine Perfusion and Normothermic Regional Perfusion (NRP) Data Collection project sponsored by the OPO Committee. The project is being led by a workgroup with members from the Data Advisory (DAC), Heart, Kidney, Liver/Intestine, Lung, Operations and Safety, Pancreas, and Transplant Coordinators Committees and aims to add data elements covering modern machine perfusion and NRP practices to assist with organ offer acceptance practices and outcomes analysis. The NRP data element review has mostly been completed, and work is progressing on to machine perfusion data elements.

Summary of discussion:

Discussion began with a question from the Vice-Chair asking how this data is intended to be collected in the OPTN Computer System, given concerns for a high level of burden related to manual data entry. The presenter clarified that the data fields are intended to be part of an automated upload process as most OPO's are already collecting this data but there is not a place to share it yet. Following that up there were concerns with the number of new data fields and the potential costs associated with those changes. The presenter did note the importance of this project given the lack of current machine perfusion and NRP data and shared confidence in the efforts of the workgroup to balance costs and benefits.

Another member asked if the workgroup had considered situations in which multiple modalities are utilized at different parts of the recovery and preservation process so that there are data collection capabilities throughout. A member suggested that this project would also be a good opportunity to

ensure that basic donation after circulatory death (DCD) data is also being collected such as extubation time and pulselessness, while also keeping in mind potential future procedures and data collection that may be needed. It was also suggested to consider collecting data on the use of open reservoir cardiopulmonary bypass versus ECMO in these cases as well as creating a standardized flowsheet data collection across the various procedures. The presenter did note that some of the more basic DCD data collection is already approved and awaiting implementation after Office of Management and Budget (OMB) approval, but that it would be beneficial to perform a thorough review.

The Chair noted that one of the issues that the MPSC continues to run into when reviewing cases where NRP or machine perfusion devices are utilized, is tracking which organization performed those tasks, whether it is a third-party vendor, the transplant program, or the OPO. The responsibility of incidents involving third parties falls to the member organization who is contracted with them, but from a compliance and performance improvement perspective, having data collection that establishes how many cases use these devices or techniques and who is performing the tasks will provide context for MPSC review, and potentially reveal trends pertinent to patient safety and policy development. Another member concurred with that point and added that their perspective is that in general, these cases are utilizing DCD organs that potentially would not otherwise have been utilized and that by creating a database of overall device use, the MPSC could recognize patterns concerning certain possible device failures or team failures that could be addressed. Finally, a member shared agreement with this suggestion and noted that given the current lack of data surrounding this topic, the more that can be collected, the better.

6. Require Reporting of Patient Safety Events - 2nd Post-Implementation Monitoring Report

Contractor staff provided an overview of the Require Reporting of Patient Safety Events proposal policy changes and reviewed the post-implementation plan and updates to the plan suggested by the Committee during its November 2024 meeting. Contractor staff reviewed the volume of required reports for transplant hospitals, recovery hospitals, and OPOs during the first and second 6 months post-implementation. In addition, for context, the volume of transplants, deceased donors and living donors for the two timeframes were also provided to the Committee. The number of reported events is quite low.

Summary of discussion:

No decisions were made

A Committee member suggested that a better denominator for the OPO events should include non-donors for which an ABO double verification was performed.

7. SRTR: Kidney/Pancreas Pre-transplant Mortality Evaluations

SRTR staff provided an overview of pre-transplant mortality evaluation of multi-organ candidates. This presentation is a follow-up to a previous presentation at the Committee's January meeting. The SRTR currently produces a separate kidney/pancreas pre-transplant mortality report based on the existence of a separate OPTN kidney/pancreas waiting list. The kidney/pancreas candidates do not appear in the reports for a hospital's kidney and pancreas program. Since the MPSC is not currently receiving kidney/pancreas reports, pre-transplant mortality for kidney/pancreas candidates is not being evaluated by the MPSC. For all other multi-organ candidates, the mortality of a candidate pre-transplant is included in program evaluations for each organ for which the candidate is listed.

When this information was presented to the Committee in January, the Committee favored inclusion of the kidney/pancreas candidates in the kidney and pancreas reports consistent with other multi-organ

candidates but requested that the SRTR calculate how inclusion of kidney/pancreas candidates in the kidney and pancreas reports would affect kidney and pancreas program flagging for pre-transplant mortality.

SRTR staff calculated the number for the most recent Fall 2024 cohort, which includes a two-year window of candidates from mid-2022 to mid-2024. SRTR staff recalculated the observed and expected deaths at kidney programs and pancreas programs adding in any kidney/pancreas candidate deaths and the expected deaths for kidney/pancreas candidates. This recalculation included the specialized risk-adjustment for kidney/pancreas. The hazard ratios and the programs that would be identified for review were recalculated. No additional kidney programs would be flagged for MPSC review based on pre-transplant mortality when the kidney/pancreas candidates were included in kidney program reporting. Following the inclusion of the kidney/pancreas candidates into the pancreas program evaluations, one pancreas program would be flagged where currently there are zero pancreas programs flagged. For pancreas programs, kidney/pancreas candidates comprise the majority of pancreas candidates so it is not surprising that inclusion of kidney/pancreas candidates would result in an additional flag. For kidney programs, kidney/pancreas candidates comprise a small percentage of those candidates waiting for a kidney so there is less of an effect when kidney/pancreas candidates are included.

Summary of discussion:

Decision: The Committee supported adding kidney/pancreas candidates into both the kidney program and pancreas program pre-transplant mortality evaluations consistent with how other multi-organ candidates are reflected in these evaluations by a vote of 25 For, 0 Against, 0 Abstentions.

Decision: The Committee supported adding kidney/pancreas candidates into both the kidney program and pancreas program pre-transplant mortality evaluations consistent with how other multi-organ candidates are reflected in these evaluations by a vote of 25 For, 0 Against, 0 Abstentions.

Committee members noted it was important to make sure that all candidate mortality is reviewed. Following review of the data, Committee members continued to support inclusion of the kidney/pancreas candidates in the kidney and pancreas program evaluations consistent with how candidates for other multi-organ transplants are reported.

8. Performance Monitoring Enhancement

Contractor staff provided an update on the implementation of the Update Criteria for Post-Transplant Graft Survival Metrics proposal, noting that the proposal was implemented today and that the data that will be presented in the next set of slides reflects the updated criteria for the two post-transplant graft survival metrics. Data was presented on:

- The number of performance flags in the Fall 2024 SRTR MPSC reports by organ, metric and overall.
- The number of individual active programs that were flagged under the four MPSC performance metrics.
- The number of performance flags by metric and organ separated by adult and pediatric.
- The number of performance flags by metric and cycle for the last 4 SRTR reporting cycles.
- The number of performance flags by organ and cycle for the last 4 SRTR reporting cycles.
- The number of individual programs flagged over multiple reporting cycles versus those that were newly flagged in the Fall 2024 reporting cycle.

As a follow-up to the Committee discussion in December 2024, contractor staff described the current process for notifying members that their program falls within the performance improvement or yellow zone. The current process requires that contractor staff draft and send memos to members informing them that their program is in the performance improvement (yellow) zone and encouraging them to review their data for potential improvement. Member feedback on these memos has been mixed with some indicating that receiving the memo is more confusing than helpful. Based on the Committee's request in December, an alternative option was provided to suspend sending notification memos and include a footnote in the SRTR MPSC reports on the SRTR secure site that indicates that the program is in the yellow zone and that resources can be found on the OPTN website.

Summary of discussion:

Decision: The Committee supported the proposed change to include a note on the SRTR secure site MPSC report to notify members that a program falls within the performance improvement (yellow) zone.

The Committee Chair noted that the flagging numbers reflect the MPSC's shift away from activity on the post-transplant side to focus on the pre-transplant metrics, particularly offer acceptance. An SRTR representative noted that the change in the MPSC focus was based on feedback from the public and the transplant community. Focusing more on the pre-transplant side, and specifically offer acceptance, promotes an increase in transplants. Additionally, the offer acceptance metric is the more risk-adjusted metric and is the metric that the transplant program has the most control over. The Chair noted that focusing on the offer acceptance metric also supports efficiency in the system, a topic that is receiving a lot of attention in the current environment.

Decision: The Committee supported the proposed change to include a note on the SRTR secure site MPSC report to notify members that a program falls within the performance improvement (yellow) zone.

Committee members expressed support for this change that would continue to notify members when a program falls within the performance improvement (yellow) zone and optimizes staff time without significant decrease in member service.

9. MPSC Education/Communication Initiatives and Policy Referrals

OPTN staff facilitated a discussion of the MPSC on previous policy referrals, potential new policy referrals, recent relevant policy changes and implementations, updates made to OPTN compliance and monitoring documents, and topics for the MPSC chair email. Staff discussed each ongoing effort and the MPSC had questions and offered feedback.

Policy Referrals

OPTN Staff provided an overview of the referral process, highlighting the information the MPSC needed to align on in order to send a policy referral. To date, the MPSC has sent 16 referrals to nine policy committees since the development of this process in early 2023. Of the 16, three referrals have results in projects that have been implemented, 10 are in development or pending approvals, and three are on hold or not approved by the OPTN Executive Committee. Staff provided updates on the following referrals:

- Clarify Discrepant ABO Typing Post-Transfusion
    - Joint referral to the Histocompatibility and Operations & Safety Committees in December 2024

- Pediatric Heart Data
    - Joint referral to the Pediatric and Heart Committees in December 2024
- Clarify Requirements for Reporting Post-Transplant Diseases
    - Referred to the DTAC in March 2023 and currently out for public comment.
- Monitoring Ongoing eGFR Modification Policy Requirements
    - Joint referral to the Minority Affairs and Kidney Committees in March 2024 and currently out for public comment, sponsored by the MAC.

MPSC members did not have any questions about the existing referrals or the referral process. OPTN staff introduced topics that were identified as potential opportunities for MPSC referrals.

Qualified Health Professional

Policy defines a Qualified Health Professional as "a person who is qualified to perform blood type reporting or verification requirements as defined in the OPO, transplant hospital, or recovery hospital written protocol." This term is currently referenced in the following OPTN policies:

- 2.6.C Reporting of Deceased Donor Blood Type and Subtype
- 2.14.B Pre-Recovery Verification
- 3.3.B Reporting of Candidate Blood Type
- 13.6.B Requirements for Match Run Eligibility for Potential KPD Donors
- 14.5.C Reporting of Living Donor Blood Type and Subtype

Summary of discussion:

Decision: Send a referral to the OSC to initiate a workgroup on developing competencies for qualified health professionals and staff will look into alternatives for education and webinars.

A member shared their previous experience in developing this definition and the associated policy. At the time, the group considered, and initially proposed, the specification of 'licensed' health professionals but agreed that this term would create an undue burden on the transplant community by excluding individuals who were competently and successfully performing these duties. A member commented that licensure would be feasible for transplant/recovery hospitals and laboratories so it may only be a barrier for OPOs.

Highlighting the possibility that an individual could become 'qualified' simply by watching a video on the topic, a member proposed developing competencies for the skills necessary to complete this work. A member considered the possibility that the competency completion could result in some type of certificate. Multiple members voiced support for competency training and assessments, noting the use of online simulation training and competency assessments at their programs. A member commented that holding a license does not mean an individual is competent in this work and a better parameter for qualification would be competency.

In considering how the idea of competency assessments should be operationalized, the Chair noted that the transplant members who are currently successfully doing this would be the ideal individuals to guide this work. However, the MPSC needed to consider if this work was a better fit for a transplant society/association, or if the OPTN was the appropriate body to house and drive this work. If the OPTN is the best place for these training courses to be held, how should it be integrated into and required by policy?

A member also recommended the possibility of system access based on the completion of competency training. For individuals who have completed the training, they would be added to a system user group

that would permit their account to enter and verify blood typing. Individuals who did not complete the training requirements would not be granted this permission and therefore unable to add and verify ABO. A member mentioned security requirements that have recently been implemented in OPTN policy that require individual user training and subsequent attestations as a framework for what could be done for training requirements for ABO. Additionally, there are other areas where the OPTN policy requires an organization to have certain minimum standards within their own internal policy to address areas of concerns.

A member expressed concern about the potential for a slippery slope here, where specific user permissions were required for a multitude of tasks, like HLA entry, eGFR validation, wait time modifications, etc. The Chair noted that there is a continuum based on the potential for direct and immediate graft failure based on the discrepancy, which would be more prevalent for ABO and HLA typing compared to eGFR validation or wait time modifications.

Alternatively, a member suggested that the long-term goal of OPTN modernization should be programming and technical solutions that are more aligned with what is clinically possible and reflective of the process as it exists. The member noted that there are currently programs that have successfully integrated various IT automation components, which streamline their work. The broader community has the ability to learn from these best practices.

The Committee considered whether minimum training requirements and attestation process could be the optimal policy solution, however, there was no consensus on this recommendation. There was consensus that requiring licensure is not the solution here, but perhaps a workgroup led by the Operations and Safety Committee (OSC) with involvement from the MPSC and Histocompatibility Committee to discuss this topic would be the appropriate next step.

Next Steps

Staff are going to evaluate the opportunities for innovative collaboration, educational efforts, webinars, and guidance documents to address the shorter term needs the MPSC has identified.

OPO Machine Perfusion Project Feedback

The Committee discussed and finalized their feedback for the OPO Committee's Machine Perfusion project.

Summary of discussion:

Members discussed the possibility that an organ could be placed on multiple devices between procurement to transplantation, between the operations from the OPO and transplant hospital. Members agreed that there should be multiple opportunities to enter the device usage on behalf of both the OPO and the transplant hospital. Members felt that this work was very important and the MPSC would be interested in having ongoing engagement with this work given its relevance to the Committee's compliance review. A member recommended discrete fields on organ recovered and placed to provide a more concrete discard rate. A member also recommended the inclusion of 'hematocrit' to provide a comprehensive understanding of donor care. Members discussed how data can be used to understand how care was provided to the donor to inform a surgeon's decision on whether or not to accept an organ offer.

Third Party Vendors

The Committee has had ongoing interest and discussions in how to handle third party vendors through their monitoring and oversight activities.

Summary of discussion:

The Committee started its discussion by identifying vendors by various buckets of work they do. Members initially identified surgical recovery (surgeon, organ preservationists), machine perfusion, transportation, contracted coordinators, TEIDI data collection, and offer acceptance screening. Alternatively, a member recommended collating a list of vendors and then organizing them into various categories. There was group support for this idea, and it was recommended as a potential first task for an MPSC Third Party Subcommittee. Members recognized the need for a living document that could be updated based on the addition of new vendors and change in practices. Members also discussed that OPOs use labs for various testing and depending on whether its histocompatibility or ABO will inform if the lab is acting as an OPTN member or as a contracted vendor.

In the current environment, the MPSC's goal is to optimize patient safety by understanding who is involved in the process of donation and transplantation. As the OPTN modernizes, the Committee feels it is essential to consider ways for all involved in the process to be accountable through the OPTN. A member proposed if it would be possible for contract vendor language to require accountability to OPTN policies and standards. In this scenario, contracted vendors would have the same level of accountability as OPTN members by virtue of their contract, acting as a proxy for the OPTN member that they are working for. Considering the current limitations in revising the membership requirements, the MPSC could develop a guidance document with best practices for third party vendor contracts to enhance accountability and engage in QAPI efforts.

Additional Policy Referrals – Heart Review Board

Committee members were asked if there were any other policy referrals they would like to discuss. A member brought up the retrospective nature of the Heart Review Board for the potential for patients to be transplanted at a denied status.

Summary of discussion:

Decision: Send a referral to the Heart Committee to do a comparative review of their retrospective Heart Review Board and the quantity of patients being transplanted at a denied status compared to other organs' review boards.

A member shared their thoughts that candidates with pending exception requests should remain at their current eligible status while their exception is under review. To mitigate patient harm, it is imperative that the Heart Review Board has a faster turnaround time in reviewing cases if they were prospective. Members noted that this is an issue with retrospective review boards, but the potential for being transplanted at a denied status could be unique to the heart community. A member specified that this concern or potential for misuse is not seen within the pediatric review board process and the group agreed that this conversation was framed around the adult heart review board. The Chair recommended the following data be considered:

- What percentage of exceptions are ultimately approved?
- What's the median and numeric range of days to approval?
- How many patients are transplanted with a status that is subsequently approved?
- How many patients are transplanted with a status that is subsequently denied?

A member shared their surprise to learn that kidney medical urgency requests were also reviewed retrospectively. The group noted that they had not received these types of reports from other organ types but recommends a comparison of data across organs to further determine if this is an isolated

issue and consider ways for improvement. A member also noted the challenge for exceptions for candidates listed for multi-organ combinations and the impact that a lower heart status can have on patients who are listed for a heart-lung with the lung being their primary organ.

Next Steps

The MPSC decided to make a referral to the Heart Transplantation Committee with a request to evaluate trends of other retrospective review boards.

Policy Project Updates

Staff provided a brief update on policy projects that are relevant to the MPSC's monitoring activities.

Require Reporting of HLA Critical Discrepancies and Cross Matching Events to the OPTN

The Histocompatibility Committee's proposal implemented on March 5, 2025, adds new required reporting for labs to submit to the OPTN Patient Safety Reporting Portal. These cases will be reviewed by the MPSC Histocompatibility Subcommittee.

Update – Aligning OPTN Policy with HOPE Act

The HIV Organ Policy Equity (HOPE) Act requires research criteria for transplantation of organs from HIV-positive donors into HIV-positive candidates. The HOPE Act was updated in November 2024 following changes to the Health and Human Services (HHS) Final Rule, which requires modification to OPTN Policy for alignment. The DTAC will distribute a policy proposal for a 30-day public comment period in mid-March, and it will proceed to the June OPTN Board of Directors meeting for consideration.

Summary of discussion:

A member inquired if these changes were specific to abdominal transplant, or inclusive of thoracic organs as well. The presenter clarified that these changes impact kidney, liver, and liver-kidney transplants but IRB requirements will remain intact for all other organs. A member inquired about consideration of HIV tests that result in false positives that require allocation through the HOPE Act. The member shared variable practices from OPOs in making a final determination on HIV results and the existence of flags in the system that result in further inquiry on OPOs. The DTAC has received this feedback previously, but unfortunately, they are unable to make these changes at the time. The presenter noted the MPSC sent a referral to the DTAC in 2023 to address this, but they were ultimately unable to proceed due to various limitations. A member echoed these sentiments, noting that modifications could be made to policy that change the requirement from 'a positive HIV test result' to 'infected with HIV' without algorithmic changes from the CDC. Additionally, a member mentioned research that has been done regarding the number of false positive organs that have been allocated through the HOPE Act, which ultimately limits the ability to utilize the donor's gift due to a smaller candidate pool. A member highlighted that difference in testing methods and variation in result interpretation could lead to false positives.

Member Monitoring and Compliance Resources: Membership & Management Policy and Bylaw Update

The Committee received an overview of the split in the OPTN Bylaws into the OPTN Membership & Management Policies. As such, the OPTN Member Evaluation Plan and corresponding MPSC monitoring resource documents have been updated to reflect these changes.

MPSC Chair Email

The Committee reviewed past MPSC Chair email topics and discussed the key takeaways from the multi-day meeting to share back to the community. OPTN Contractor highlighted some previous, relevant

messages that the MPSC has shared in order to further refine and add more granularity to this chair email.

Summary of discussion:

A member recommended a more in depth call out to the MPSC Chair email topics during OPTN Regional Meetings to emphasize the importance of the topics in the email, especially since so many of them are patient safety related.

Through case review, a member identified an increase in instances where Histocompatibility labs were importing incorrect data files for donors, which were ultimately used for allocation and the inaccuracy was identified during crossmatch, prior to transplant. In each of these instances, the labs completed testing accurately but uploaded testing results from the incorrect donors. While none of these instances led to an incompatible transplant, they all impact the efficiency of the allocation process and can be mitigated. The Committee agreed to include this topic in the chair email.

The Committee continues to see that programs have challenges with accurately reporting ABO information. A member recommended soliciting members to volunteer to engage in a discussion on their best practices for IT automation solutions for ABO imports. This could include a member sharing how their IT department identified and implemented the optimal solution for their program, which increased efficiency and decreased manual errors. Members recommended embedding a REDCap or Microsoft Form link into the email for individuals to volunteer easily. Members agreed to include this topic.

During the previous day's meetings, the topic of reviewing offers in a timely manner was flagged for the Chair email. This is not only a policy requirement but also has potential for downstream impacts where late declines could lead to an increase in allocation out of sequence (AOOS). Members recommended mentioning the responsibility of primary offer holders to review all of the information in the offer, consider if the patient is ready for transplant, and ensure that the final decision maker on the acceptance has reviewed the details. Members agreed to include this in the Chair email.

The Committee has had ongoing conversations about the involvement of third-party vendors in the transplantation process. The MPSC wants to continue to reiterate the responsibility of OPTN members for the actions of their vendors, but they do not want members to be deterred from reporting actions of third parties. As the MPSC considers how these organizations could be integrated into the OPTN through modernization, it is imperative that they have a holistic understanding of the types of groups involved and where needs for monitoring exist. Members agreed that this is relevant and recommended additional granularity in the messaging.

A member recommended the potential to address, or at least acknowledge, the AOOS directive from HRSA. The Chair agreed that it felt appropriate to acknowledge the continued growth of AOOS and identify this as a symptom of how allocation and transplant can be optimized. The group considered what types of guidance could be given to programs or OPOs on ways to avoid AOOS. Some of the recommendations are thoroughly reviewing organ offers (as mentioned above), lower than expected offer acceptance rates, the intricacies of a multi-vendor environment, and the utilization of center wide offer filters and individual acceptance criteria to declutter the system. A member also highlighted challenges associated with local back up offers, who ultimately decides an organ is transplanted out of sequence (i.e., transplant hospital vs OPO), and how this information is documented on the match run. A member also recommended that this could be an opportunity to dispel some of the false information that has been circulated regarding AOOS and review.

The Chair recommended highlighting that the change in MPSC metric threshold for post-transplant outcomes was implemented during the meeting. This shift in threshold had the intended outcome of reducing the number of programs flagged and allowed the MPSC to shift its attention to offer acceptance rate which dovetails to ongoing conversations on efficiency, organ non-use, and AOOS.

Other Educational Referrals and Ideas

A member shared their upcoming speaking engagement on a panel on patient safety and third-party vendors. Another member shared the ongoing concerns they are hearing from the community around the lack of transparency from HRSA with the Regional Meetings being moved to virtual only and the removal of the OPTN Board of Directors. Members agreed that they would like more communication from HRSA on what is happening next with contract transitions and modernization of the OPTN. Members shared concern and confusion on the continuation of terms for Associate Regional Councilors who are on the MPSC. A member commented that instead of modifying the OPTN Computer System in a piecemeal manner, it would be more beneficial to do a holistic system review and revision.

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 seven transplant programs: one heart program for 1-year conditional; one kidney program for 90-day; three liver programs for 90-day, one liver program for 1-year conditional; and one pancreas program for 1-year conditional. Additionally, the Committee approved the release of monitoring of 23 transplant programs: five heart programs for 90-day, three heart programs for 1-year conditional; three kidney programs for 90-day, three kidney programs for 1-year conditional; three liver programs for 90-day, three liver programs for 1-year conditional; two lung programs for 90-day; and one pancreas program for 90-day.

For transplant programs under review for offer acceptance, the Committee approved the continued monitoring of 10 transplant programs: nine kidney programs and one lung program. Additionally, the Committee approved the release of monitoring of 10 transplant programs: four kidney programs, three liver programs, and three lung programs.

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

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

For organ procurement organizations (OPO) under review for donor yield, the Committee approved the continued monitoring of one OPO.

The Committee approved the consent agenda by a vote of 31 For, 0 Against, and 0 Abstentions.

The Committee also discussed cases in closed session.

11. Compliance Issues

The Committee reviewed a consent agenda consisting of 10 transplant programs that had undergone a focused desk review during this cycle, including one heart program, one kidney program, one living donor kidney component, three liver programs, one lung program and three pancreas programs. The

Committee released six of those programs from monitoring and recommended focused desk reviews for four programs. The Committee also reviewed six OPOs for allocation errors, all of which were closed with no action. The Committee reviewed 62 case investigations during this cycle, consisting of member complaints or self-reported potential policy violations. The Committee issued 34 Notices of Noncompliance and closed 28 issues with no action, 20 of which were closed for self-reporting. In addition, the Committee reviewed 20 reported living donor events this cycle. Twelve events were aborted nephrectomies, 11 of which were reported within required timeframes and closed with no action, and one of which was issued a Notice of Noncompliance for late reporting. One aborted hepatectomy was also closed with no action for appropriate reporting. There were four living donor redirections; all reported on time and closed with no action. In addition, three living donor deaths were reviewed and closed with no action. The Committee approved the consent agenda by a vote of 30 Yes, 0 No, and 0 Abstentions.

The Committee also discussed cases in closed session.

12. Membership Issues

Decision 1: The Committee reviewed and approved the consent agenda

The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it meets in closed session and considers actions regarding the status of current members and new applicants and applications are presented to the MPSC members as either a consent or discussion agenda. The Committee reviewed and approved the consent agenda by a vote of 29 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 June 2025 meeting.

- Approve 1 New Transplant Hospital
- Approve 1 New Transplant Program
- Approve 1 New Living Donor Component
- Approve 1 Transplant Component Reactivation
- Conditionally Approve 1 Pediatric Component
- Approve 1 Business Membership Renewal

The Committee also reviewed and approved the following personnel changes.

- 4 Applications for New Key Personnel for Transplant Programs or Components
- 8 Applications for Changes in Key Personnel for Transplant Programs or Components

Upcoming Meetings

- 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**
  - 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
  - Nicole Hayde
  - Kyle Herber
  - Michelle James
  - Christy Keahey
  - Glen Kelley
  - Lindsay King
  - Varvara Kirchner
  - Kevin Koomalsingh
  - Kevin Korenblat
  - Peter Lalli
  - Scott Lindberg
  - Maricar Malinis
  - Deborah Maurer
  - Luis Mayen
  - Deborah McRann
  - Clifford Miles
  - Saeed Mohammad
  - Deirdre Sawinski
  - Malay Shah
  - Nirmal Sharma
  - Zoe Stewart Lewis
  - Carrie Thiessen
  - Mark Wakefield
  - James Yun
- **HRSA Representatives**
  - James Bowman
  - Diane Brockmeier
  - Shantel Delgado
  - Marilyn Levi
  - Raymond Lynch

    - Joni Mills
    - Arjun Naik
    - Kala Rochelle
- **SRTR Staff**
    - Ryo Hirose
    - Grace Lyden
    - Jonathan Miller
    - Jon Snyder
    - Bryn Thompson
- **UNOS Staff**
    - Anne Ailor
    - Robert Albertson
    - Sally Aungier
    - Jadia Bruckner
    - Matt Caffarella
    - Robyn DiSalvo
    - Nadine Drumn
    - Laureen Edwards
    - Katie Favaro
    - Liz Friddell
    - Caroline Hales
    - Asia Harden
    - Houlder Hudgins
    - Robert Hunter
    - Elias Khalil
    - Krissy Laurie
    - Rebecca Murdock
    - Heather Neil
    - Delaney Nilles
    - Emily Powell
    - Tina Rhoades
    - Sarah Roche
    - Liz Robbins Callahan
    - Melissa Santos
    - Laura Schmitt
    - Erin Schnellinger
    - Sharon Shepherd
    - Courtney Skeen
    - Sarah Stevenson
    - Stephon Thelwell
    - Tamika Watkins
    - Betsy Warnick
    - Emily Womble
    - Hobie Wood
    - Karen Wooten
    - Amanda Zamora
- **Other Attendees**
    - PJ Geraghty