OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Meeting Summary

OPTN Membership and Professional Standards Committee (MPSC)
Meeting Summary
November 1-3, 2023
Chicago, Illinois

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Introduction

The Membership and Professional Standards Committee (MPSC) met in-person in Chicago, and via Webex in both open and closed session on November 1-3, 2023. The following agenda items were discussed during the open session of the meeting:

1. Histocompatibility Committee -Required Reporting Project
2. Histocompatibility Committee - Critical Discrepancy Referrals
3. Annual Review of Operational Rules and Additional Monitoring Process Discussion
4. Requirements for Patient Safety Reporting Implementation
5. Site Survey Update: Continuous Monitoring
6. OPO Conflicts of Interest Issue
7. Network Operations Oversight Committee (NOOC) - General Update
8. Performance Monitoring Enhancement (PME) project update
9. OPO Performance Monitoring Project
10. Task Force on Expeditious: Organ Usage through Placement Efficiency
11. Report of Investigative Activities
12. MPSC Brainstorming: FDA Oversight of Perfusion Devices
13. Membership Bylaw Revisions
14. Modify Waiting Time for Candidates by Race inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations Compliance Update
15. MPSC Education/Communication Initiatives and Policy Referrals

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

1. Histocompatibility Committee - Required Reporting Project

The Chair of the OPTN Histocompatibility Committee presented their project to require histocompatibility laboratories to report critical human leukocyte antigen (HLA) discrepancies to the OPTN Patient Safety Portal for medical peer review. Currently, the Histocompatibility Committee reviews donor discrepancies quarterly and can provide general community education but is unable to do targeted outreach or improvement because the data reviewed is not center-specific. The goal of this proposal is to reduce the overall number of HLA typing errors by focusing on process improvement for laboratories with a high proportion of HLA typing errors. The proposed process would involve MPSC review and adjudication of such cases. The Histocompatibility Committee anticipates approximately 70 cases per year will be reported with this policy change. The Histocompatibility Committee is interested in pursuing Summer 2024 public comment and would like feedback from the MPSC on the preliminary stage of this proposal.

Summary of discussion:

A member inquired if it would be more efficient for these reviews to be conducted by the Histocompatibility Committee, as opposed to the MPSC, due to the subject matter expertise, and then shared with the MPSC on a routine basis. A member noted the potential to align the process with the current review conducted by the Ad hoc Disease Transmission Advisory Committee (DTAC) and voiced support for consistency. The presenter expressed concern about the Histocompatibility Committee's ability to participate in medical peer review in the same manner as the MPSC, therefore, limiting their ability to review the center-specific data. The Histocompatibility Committee expressed interest in taking any steps necessary in order to undertake medical peer review. Currently, the MPSC has an MPSC/Histocompatibility Advisory Subcommittee, which reviews laboratory membership applications, but staff are exploring ways to better utilize that Subcommittee for this type of work in the future. A member commented that the addition of 60 cases per year would be manageable for the Advisory Subcommittee and this change would be a valuable addition to the current system.

2. Histocompatibility Committee - Critical Discrepancy Referrals

A member of the MPSC presented the upcoming process for the Histocompatibility Committee referring critical discrepancy cases to the MPSC. These cases have arisen through the deidentified annual review the Histocompatibility Committee conducts and are identified through discrepant data, not required reporting to the OPTN. By referring these cases to the MPSC, additional outreach can be conducted to better understand how the discrepancy occurred and what steps have been taken to mitigate future issues.

The Histocompatibility Committee reviewed 70 discrepancies out of 14,763 typings from 84 labs and found the median number of critical discrepancies per lab is one, and the median percentage of critical discrepancies per lab is 0.55%. The threshold for review and referral to the MPSC are labs with both more than one critical discrepancy and greater than 1% total critical discrepancies for deceased donor HLA typings.

Summary of discussion:

The OPTN Contractor noted the resource requirements associated with compiling the necessary information for these resources, and more substantially, for the required reporting project mentioned previously. Members are encouraged to consider the most efficient and effective system for operationalizing HLA critical discrepancy review and what type of changes would be necessary to create that process, whether that be Committee charge, policy, bylaw, and/or programming changes.

A member asked of the 70 discrepancies reviewed by the Histocompatibility Committee, how many were of clinical significance and how many were discordant results due to variable typing methods? The presenter responded that since their review is blinded, they are unable to obtain the necessary follow-up information that would determine the significance of the issue and if, or how, it has been handled. The concern, however, is that the discrepancy in typing is so severe that it could lead to clinical patient harm if it were not caught.

A member clarified the types of discrepancies as data entry errors, a failure in the test, or the wrong sample is used. Data entry errors are the most common and are being addressed through new application programming interfaces (APIs). The committee member expressed confidence that the new APIs would greatly reduce the 70 errors that could be reported, therefore, greatly diminishing the burden on the OPTN Contractor.

The Chair summarized the MPSC's feedback and support for the Histocompatibility Committee to obtain oversight of these issues to best leverage the subject matter expertise. The Chair recommended

meeting with the Histocompatibility Committee leadership to discuss these issues further as they may better align with their scope of work as opposed to the MPSC's scope.

3. Annual Review of Operational Rules and Additional Monitoring Process Discussion

Over time, the MPSC has approved processes and operational rules to make their workload smoother and to allow committee members to focus their efforts on the most significant and impactful issues. In the past, the Committee has approved these processes individually and they have remained in place unless a policy, bylaw change, or process improvement created a need to update them.

Beginning in 2022, the Committee was asked to review all approved rules and processes annually. This review is intended to increase communication and confirm that all existing rules are relevant. Staff presented each rule, providing time for the Committee to deliberate or suggest changes. A summary of each one follows.

Summary of Discussion

Decision #1: The Committee approved all existing operational rules as discussed, removing the rule pertaining to lower respiratory SARS-CoV-2 testing.

Decision #2: The Committee approved a new operational rule for first time noncompliance with failing to register a living donor recipient on the waiting list prior to transplant.

Decision #3: The Committee approved changes to the patient safety intake form.

Overall processes

- Case Review Process: Currently, MPSC members review cases through the OPTN computer system. Staff create reports and assign three or four MPSC members to an ad hoc subcommittee to review each case. When selecting MPSC members for each subcommittee, staff consider the nature of the case and appropriate subject matter expertise, any potential conflicts of interest, and committee members' availability. Staff may try to gain consensus prior to assigning the case to an agenda. A committee member expressed support for the current process but asked whether staff could limit the use of secure email in their communications. The group supported moving forward with this process.
- Process For Member Waiving Interview: As outlined in the OPTN Bylaws, Appendix L *(Reviews and Actions*), the MPSC may offer a member an interview. If a member waives an interview, staff bring the issue back to the Committee to confirm the next steps. The MPSC will review the case again, including the member's waiver of its interview to confirm the action for the issue as well as any requested documentation submissions and aspects of monitoring the Committee may want. Committee members supported this process and did not have any questions.

Performance Related

- Sending Initial Performance Inquiries: The MPSC approved an operational rule to automatically send an initial inquiry to members who are newly identified for performance review when the data is available, without a committee vote. The Committee had no questions, concerns, or suggested changes for this operational rule.
- Inactivity Review Guidelines: The OPTN Bylaws, Appendix D.11.A (*Review of Transplant Program Functional Activity, Functional Inactivity*) outline requirements for transplant program activity. The Committee previously approved the following rules to determine which members receive an initial inactivity inquiry: Is program currently active? Has the program been inactive for one

year? Is the program currently under review? Has the MPSC released the program from inactivity review in the last two meeting cycles? Did the program receive zero offers or have zero candidates on the waitlist? If the answer to any of these questions is yes, staff do not send an inquiry. During its discussion, one committee member asked for clarification on the definition of two meeting cycles. "Meeting cycle" refers to the time between the MPSC's multi-day meetings. Staff provided an example that if a member was released from review for functional inactivity at the October 2022 meeting, and the member was identified for functional inactivity before the February or July 2023 meetings, then staff would not send the member an inquiry. Staff clarified that inactivity data is based on the OPTN computer system and does not refer to SRTR data releases. The Committee had no concerns about continuing to use these guidelines.

- Outcomes Review Guidelines: For transplant program outcomes, the MPSC also approved four of the five criteria described in the functional activity section above. Specifically, the MPSC asked: Is the program currently active? Has the program not been in active status for one year? Is the program currently under review? Has the program been released from review in the last two meeting cycles? The Committee agreed to continue these rules as approved.

Application Related

- Late Key Personnel Changes: The OPTN Bylaws require members to notify the OPTN Contractor of a change in key personnel, specifically a primary physician, primary surgeon, laboratory director, technical supervisor, general supervisor, or clinical consultant. According to the first portion of this rule, if a member notifies the OPTN late of a key personnel departure but submits an application at least 30 days before the current person departs, staff will document and close the issue. Staff will educate the member on the late notification requirements. However, if the member fails to notify the OPTN within seven days after the hospital learned of a key personnel departure and fails to submit a key personnel change application at least 30 days before the current key personnel departs, the application will be posted for MPSC review. Lastly, the rule states that if a member reports a change late a second time, the case is posted for reviewers. A committee member asked about key personnel changes that involved the switch of primary surgeon or physician, but not a departure. In that case, the hospital would be required to notify the OPTN on certain timelines, but according to the OPTN Bylaws they can determine the date the change will take effect.
- Reviewing Key Personnel Change and Non-Institutional Member Renewal Applications: To reduce the committee members' workload, transplant program Key Personnel change applications and Non-Institutional Member renewals that clearly meet the OPTN Bylaw requirements are put directly on the consent agenda for approval. The Committee had no questions or concerns with these rules.
- Application Rejections on the Consent Agenda: If reviewers unanimously agree to reject an application after review, that decision is placed on the consent agenda. This operational rule was put in place after the Committee had extensive discussions about applications that clearly did not meet the OPTN Bylaw requirements, which the MPSC has no option to approve. The Committee had no questions or concerns with these rules.

Compliance Related

- Survey Evaluation Tool (SET) Implementation and Update: The SET is used to determine whether a site survey is closed with no follow-up, a focused desk review of certain policies is needed, or the survey report should be sent to MPSC reviewers. The tool separates policies reviewed into categories, based on the potential risk to patient safety. If a member does not meet the required compliance thresholds, staff automatically conduct a desk review of that policy after six

months. The MPSC evaluates the routine review and the first desk review with the SET and moves forward with that recommendation. The MPSC will review any second desk review results and any reviews with serious concerns about patient safety, compliance, or corrective action plans. The Committee did not have any concerns about this operational rule but suggested that the tool itself be presented to the MPSC periodically.

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

First Time Noncompliance Rules

- Late OPTN Report of Disease Transmissions: OPTN Policies 15.4 (*Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions*) and 15.5 (*Transplant Program Requirements for Communicating Post Transplant Discovery of Disease or Malignancy*) require OPOs and transplant programs to notify the OPTN and other OPOs and transplant programs, if they have certain specific information about or suspicion of a potential disease transmission between a donor and recipient. For members that report appropriately to other members but miss reporting to the OPTN, staff request the results of any RCA and CAP. If the member has no significant history of late reporting and the RCA and CAP appropriately address the issue, the case is closed with no action. Any subsequent cases will go to the MPSC for review and will include information on the first case involving late reporting. When the MPSC approved this rule, they also added that the "first time" rule involves a rolling three-year period, since that is the time frame staff typically apply when reporting on a member's "compliance history" with the MPSC. A Committee asked whether the rule could look at a difference in volume of events rather than strictly time, and staff will consider ways to improve this rolling three-year period.
- Waitlist Inactivity: Programs are reviewed for patient notification of periods of waitlist inactivity according to OPTN Bylaws Appendix D.12.B (*Patient Notification Requirements for Waiting List Inactivation*). Members are required to notify patients when inactivating their waitlist more than 14 consecutive days or more than 28 cumulative days in a calendar year. Staff receives a report and verifies that members notified their waitlisted patients. If they did not follow the requirements, members must implement a CAP. A first-time occurrence of noncompliance will not be forwarded to the MPSC for review. If a second event of noncompliance is identified, staff will gather documentation from the member and provide all documentation from both events to the MPSC for review. The Committee approved continuing the rule.
- Vessel Storage: OPTN Policy 16.6.B (*Extra Vessels Use and Sharing*) prohibits members from storing extra vessels if the donor tested positive for human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) according to specified tests. The current operational rule in place includes automatically closing a member's first instance of storing prohibited vessels. Should the member store any prohibited vessels again, staff will forward the information, including the first instance, to the MPSC for review. The Committee discussed the potential safety implications and the continuing discussion of potential changes to vessel policies but determined to keep this rule intact including the rolling three-year period.
- Review of Lung Donor COVID-19 Testing: OPO compliance with the policy to require lower respiratory SARS-COV-2 testing on all lung donors is reviewed in real-time. If the member did

not perform the testing, the OPO is asked to provide an explanation and develop a plan for future potential lung donors. The first event of identified noncompliance is not forwarded to the MPSC for review. If a second event of noncompliance occurs, both events are referred to the MPSC for review. The Committee discussed that this requirement is no longer new, and there is not a need for further education during the review of missed lower respiratory testing and voted to remove this operational rule.

New Proposed Rule

- Policy 3.4.C (*Candidate Registrations*) requires that all candidates be registered on the waiting list prior to transplant. Some hospitals may have patients who have living donors, and they do not intend to consider deceased donor organs for that patient. Staff monitor hospitals' compliance with this policy through a weekly report provided by the OPTN Contractor's Research department. If the recipient of a living donor kidney was not registered on the waiting list prior to transplant, then staff will send an inquiry to the hospital to investigate. Staff will ask the hospital to provide an explanation and a plan for future candidates. This rule is proposed to close the first identified event for each hospital, without forwarding to the MPSC for review, and communicate to the member that any subsequent event would then be forwarded on for committee review. In that review, the MPSC would receive information about the first event as well as the second. This process is consistent with other first-time noncompliance practices. The Committee agreed that this process should be implemented and approved a rolling three-year period for this rule as well.

Continued Discussion of Intake Form

Staff presented changes to the Compliance and Safety Investigation Triage (Intake) Form, which were incorporated based on feedback and recommendations Committee members made at the July meeting. Changes include adding issues of incorrect HLA into the assessment of significant harm or potential for significant harm, reordered questions that lead to determination of risk, a standardized assessment for identifying issues outside of OPTN purview, and assessment for consistent referral to other areas that perform routine monitoring. The changes also included a revision of the member involvement in investigations in the past six months identification to upgrade from a risk level 3 to and risk level 2, the removal of risk level 4 entirely, and further clarification of the requirements for member and leadership contact. Staff explained that risk level determinations have no effect on committee adjudication.

4. Requirements for Patient Safety Reporting Implementation

Staff informed the Committee of minor changes to the reporting process once this policy is implemented. The only change in the reporting process is that the Patient Safety Portal will now include a list of the events this policy requires be reported within the required timeframe. The intake and investigation process will remain the same, and the risk level will be determined by the circumstances of the event itself, notwithstanding the fact that the report is now required.

5. Site Survey Update: Continuous Monitoring

Site Survey staff presented an update on the continuous monitoring process. First, the team covered the routine monitoring process as a reminder. Every transplant hospital and OPO is surveyed once every three years with additional focused follow-up review as needed based on compliance rates. Up to two focused desk reviews are conducted, each done six months after the last review. Focused review results are sent to the MPSC for resolution when continued non-compliance is observed. Routine surveys include a record review of random sample plus process/protocol review and education.

Next, the team covered what value the continuous monitoring process adds. This process directly relates to the mission of OPTN contractor's Member Quality department to keep patients safe, keep

members informed and supported for success. The process provides committees with compliance trends with new policies and if additional communication or education is needed to support members. It also identifies knowledge gaps and helps to course correct quicker. Lastly, it promotes efficiency of Waitlist and DonorNet.

The team has begun revising the timeline for second focused desk reviews by contacting members before requiring the second desk response, giving more feedback, and providing a contact for follow-up questions/concerns. Additionally, the team is collecting automated reports from the OPTN Contractor's Research Department that are released when there is system activity where monitoring and member support are identified. The current Waitlist Management reports cover the following topics: Kidney Safety Net eligibility for prior heart, liver, and lung recipients; calculated panel reactive antibody (CPRA) unacceptable antigen forms; externally verified deaths of patients still listed on the Waitlist; and multi-listed candidates removed for transplant at one hospital and still listed at others. The team is currently receiving one DonorNet report for COVID lower respiratory testing (LRT) in lung donors. The team shared ideas for future monitoring. The team is considering reviewing required source documentation uploaded to DonorNet, currently part of the routine survey process, and considering moving this review to a rolling and ongoing basis. The team is also currently developing an annual report of vascularize composite allograft (VCA) activity that will prompt any needed comprehensive monitoring on both the donor and recipient sides.

The team was proud to share recent success stories with the Committee. Regarding monitoring of COVID LRT after the emergency policy was implemented on May 27, 2021, we know that pre-implementation only 60% of lung donors were being tested using LRT. Post-implementation, 99% of transplanted lung donors have had LRT. Thus, the team will institute a process change based on this successful compliance rate; the team will change from monitoring 100% weekly to a random sample of 50% of lung donors monthly. When the team began monitoring the report of kidney patients who were missing a signed CPRA Unacceptable Antigen Form, there were 42 patients with greater than 90 days outstanding where they could have been receiving priority had that signed form been entered in Waitlist. Within one month of monitoring the report and reaching out to members, 40 patients began receiving the appropriate priority. The team has also seen a significant impact on the report of Verified Deaths of Patients still listed in Waitlist. At the beginning of monitoring, there were 500 patients. As of the date of this meeting, there were 240 patients remaining on the report after members were notified.

Despite the success observed, there are known challenges with this new process. Members may experience communication fatigue due to more frequent requests from the Site Survey team. There are certainly limitations with the secure file sharing site and the team will continue to advocate for improvements. Additionally, there is not currently a place for members to upload source documentation in Waitlist as exists in DonorNet.

Lastly, the team shared the next steps and asked for feedback and questions. A committee member suggested focusing on high-risk safety areas. The committee member also pointed out that it is important to be efficient while also being mindful of available resources. The committee member pointed out that the focus should not necessarily be where we are able to focus efforts but where should we be focusing our monitoring efforts. Another committee member suggested that this presentation be shared with the OPTN Transplant Administrators Committee (TAC) and quality staff. Staff appreciated that suggestion and will coordinate with the TAC support staff to do so.

6. OPO Conflicts of Interest Issue

The current MPSC process is to assign committee members cases to review based on the need for subject matter expertise. Transplant hospital, OPO, and Histocompatibility lab members are all assigned

cases for all types of members, but staff make sure that each case is assigned to some MPSC members from the same type of institution. When assigning cases, staff also check for potential conflicts of interest for reviewers. Specifically, the MPSC follows the OPTN requirements for confidentiality and conflict of interest. Staff assign cases avoiding a committee member's regional colleagues, previous employers, or other expressed conflicts. Committee members are also encouraged to self-disclose potential conflicts that staff would not otherwise be able to identify, such as personal relationships or business relationships that were not previously disclosed by the committee member.

The upcoming implementation of the Centers for Medicare and Medicaid Services (CMS) 3-tier system and process for OPO recertification, including the opportunity for OPOs to apply for other donation service areas (DSA), has raised a question of a potential effect on MPSC processes. Before this process begins, the MPSC discussed whether there is any concern that members of the MPSC who work at OPOs may be privy to confidential business information of OPOs under review, in the interest of transparency.

Summary of Discussion

Committee members were asked to respond to the following questions:

- Is peer review of OPOs an effective practice?
- Do we need OPO peers to be a part of OPO peer review?
- Do we need to have OPO peers for improvement purposes?
- We already control regional conflicts, etc., but the DSA bidding is not restricted to region. Is there information available in case reviews that might be considered helpful if an OPO was planning to apply for another OPO's DSA?
- Can CMS share who is bidding on DSAs so we can exclude potentially competitive OPOs as a conflict if necessary?
- Are the current OPTN conflict standards and attestations sufficient for the future state?
- If not, what suggestions does the MPSC have for conducting reviews of OPO performance and compliance in the future?

Committee members all agreed that peer review by other OPO committee members was crucial to the MPSC's process and member improvement. OPO peers are important to the process for their perspective. A committee member asked whether current peer reviews are really revealing much information that OPO members did not already know, and how much of a concern is this issue. The potential for conflicts has been brought up by HRSA as well as member OPOs, so having a well-reasoned answer will be important. A committee member suggested that adjacent OPOs may already be working together to have mutual gains, and cooperation overall would be better than competition. In addition to the concern that reviewers may be looking at information on members who are eligible for decertification, a committee member posed the question of whether OPO peers should be in the position of having to help what could be seen as their competition. Committee members felt that the commitment of the MPSC is to help improve member processes and peer review is a key part of that. Overall, committee members did not believe that there is much advantage gained by being a peer reviewer on MPSC cases.

Committee members discussed the potential for increased communication with HRSA and CMS as the changes are implemented. A committee member suggested potentially engaging with CMS to continue these discussions of potential conflicts of interest. A committee member questioned whether the CMS process is going to affect the work that the MPSC does. The consensus was that it may not directly affect MPSC cases and processes but will change the landscape of and work for OPOs in the country. The OPTN is likely to know only how many OPOs exist and what their coverage is but will not be part of the bidding

or transfer process. The MPSC will need to get as much information as possible as this process continues to try and help minimize confusion and disorder.

Committee members discussed potential changes or additions to the conflicts of interest policy. The MPSC discussed several issues: whether OPO peers should self-report if their OPO has interests in the OPO being reviewed; whether there should be a modified disclosure that is signed by MPSC members; and whether OPO reviewers could recuse themselves without giving a specific reason if there is a conflict of interest based on upcoming CMS changes. It is important for the MPSC, especially during the peer visit process, to remain focused on patient safety and reviewers should avoid digging into other processes, which limits these concerns. Overall, the committee felt that there is more concern about the perception to the public of a conflict of interest than there is any practical advantage to being an MPSC reviewer, but acknowledged the need to keep engaging in this discussion as the process moves forward.

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

OPTN Staff presented on the project to Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements sponsored by the NOOC. Phase one required members to identify two Site Security Administrators and an Information Security Contact by July 31, 2023. Any members remaining noncompliant will be referred to the MPSC for review. Staff requested MPSC feedback regarding what information will be needed from NOOC for the reviews and if the MPSC would support closing cases without review if staff are able to get members into compliance.

Summary of Discussion:

Members moved to support closing cases without review if staff can get members in compliance. The Vice-Chair suggested setting a timeframe for staff to try to bring the members into compliance prior to MPSC review and another member recommended thirty days, after noting the low lift effort required to come into compliance on this.

8. Performance Monitoring Enhancement (PME) project update

In December 2021, the Board of Directors, on the recommendation of the MPSC, approved the new transplant program performance monitoring system that expands the metrics the MPSC uses to evaluate transplant program performance from two to four with a phased implementation. The four new metrics are intended to survey processes occurring both before (pre-transplant mortality rate and offer acceptance) and after transplantation (90-day post-transplant graft survival rate, 1-year post-transplant graft survival rate conditional on survival beyond 90 days).

The Committee was provided with both a detailed written Annual Post-Implementation Monitoring Report and a high-level presentation of the data. The report outlines the specific populations and outcomes that will be periodically monitored to detect potentially unintended consequences to the transplant system. Subsequent reports will include additional outcomes to evaluate and monitor system performance relative to the implementation of these bylaws changes. Staff explained that this report may evolve over time as more data becomes available and the bylaw changes are fully implemented.

OPTN Contractor staff also reminded the Committee that, as part of the post-implementation monitoring, the Committee is provided data on the number of programs identified by each metric and the number of unique programs identified at every winter and summer MPSC meeting coinciding with the release of the program specific reports by the Scientific Registry of Transplant Recipients (SRTR).

Finally, the Committee was provided an update on the results of the OPTN Offer Acceptance Collaborative.

Data Summary:

- Deceased donor utilization rates indicate no change (kidney, pancreas) or increases/stabilization (liver, heart, lung) compared to forecasted trends.
- Waiting list registration additions indicate no change (kidney, pancreas/kidney-pancreas, lung) or increases (liver, heart/heart-lung) compared to forecasted trends.
- No concerning trends in one-year all-cause graft failure rates
- The data did not identify any negative, unintended consequences and might have improved the system slightly.

Summary of discussion:
Committee members had questions about the utilization rate data and noted that the presentation format for the utilization rate was unclear and unhelpful in determining whether the proposal resulted in an increase in the number of transplants or resulted in an unintended negative effect on utilization. Committee members expressed concerns that there was not sufficient context in the data for the utilization rate and was not understandable for non-statisticians. The numerator used for the organ-specific utilization rates is any donor for which at least one organ, any organ, was recovered for transplant. The Committee noted that the analysis was complex and asked that the report be modified to be more understandable to non-statisticians before they are made available outside of the committee. Committee members requested that OPTN Contractor staff consider the following suggestions to make the data more understandable:

- Putting the equation at the top of the graphic and adding an interpretation on some of the graphs.
- Changing to organ used over the number of that organ recovered instead of total donors so that for example, the utilization of a heart is not being evaluated based on whether a kidney was recovered from a donor when there would be no expectation that a heart would be utilized.
- Superimpose the actual number of transplants going up for each organ so that the increasing rate of transplant is clearly shown.
- Providing a clearer explanation of the counterfactual so that it is easily understood.
- Look at kidney utilization by kidney donor profile index (KDPI) stratifications.
- Make the overall message that the implementation of the metrics has not harmed the system and might have helped slightly.

A Committee member asked why the post-implementation evaluation looks at 1-year graft survival rather than the 90-day graft survival and 1-year conditional on 90-day survival separately. OPTN Contractor staff responded that since the post-implementation monitoring is intended to evaluate system-level effects of the proposal, the MPSC thought that, during the development of the post-implementation plan, reviewing 1-year graft survival would be sufficient to evaluate effects of the proposal post-transplant outcomes. The 1-year graft survival is used for an initial system-level evaluation and if there are concerning trends in that 1-year data, the Committee could review 90-day and 1-year conditional on 90-day survival to further evaluate the trend.

Next Steps:

OPTN Contractor staff reviewed the next steps for this project. The pre-transplant mortality metric is scheduled for implementation in July 2024. Following an overview of the MPSC's purpose for including this metric, staff reviewed the steps and timeline for development of educational materials and the questions the Performance Monitoring Enhancement Subcommittee will be considering in the next several months as it is developing the recommended MPSC review process for programs identified for higher-than-expected pre-transplant mortality.

9. OPO Performance Monitoring Project

An update was provided on the work of the OPO Performance Monitoring Enhancement Workgroup, which is focused on defining standard processes and consistent definitions for essential data points for the referral to authorization phases of the donation process and developing a proposal for new data collection. The Work Group is comprised of representatives of the MPSC, OPO, Data Advisory, Patient Affairs and Transplant Coordinators Committees. The goal is to develop a concept paper for Winter 2024 public comment followed by a data collection proposal based on the feedback.

The Chair of the Workgroup highlighted its progress to date:

- Reviewed two existing examples of process flows, data capture documents and data definitions. (Region 8 pilot sponsored by AOPO and a donor tracking tool used by Chair's OPO.)
- Supported development of module that incorporates logic, standard processes, and consistent definitions for essential data points.
- Supported investigating collecting data from in-hospital deaths from transplant hospitals that can be used to validate data submitted by OPOs as a demonstration project.
- Reviewed and provided feedback on two iterations of a draft OPO referral data capture tool that could be incorporated into OPOs' Electronic Donor Records (EDR).

The Workgroup Chair shared that he would be presenting to the Association of Organ Procurement Organizations (AOPO) Data Council and the Executive Forum in November. These presentations are planned to engage the OPO community early in the process so that they will be better informed on the project's goals.

The draft OPO referral tracking tool was shared with the Committee noting that the tool would allow for more granular data to be collected on every referral. The Workgroup Chair shared that logic algorithms would be incorporated into the tool to drive OPO staff to the appropriate next questions based on the staff's answers to yes/no questions as they move through the referral and potential donor evaluation. The incorporation of the algorithms removes much of the decision making and judgement calls that currently are made by frontline staff. The use of this tool would mean that OPO staff in the field would all be capturing data the same way using the same definitions leading to a higher level of consistency and data integrity.

In addition to the data capture through the tool, the Workgroup Chair presented examples of the algorithms for the following potential donor referral outcomes:

- No Potential for Organ Donation: Not Medically Suitable
- No Potential for Organ Donation: Not Brain Dead, Not a DCD Candidate
- Potential Organ Donor: Next of Kin Decline
- Potential Organ Donor: Patient Arrest
- Potential Organ Donor: Medical Examiner/Coroner Decline
- Organ Donor

Benefits of the tool include:

- Collection of this information will allow OPOs to provide feedback to individual hospitals about their performance.
- Improved understanding of donor potential for complex/DCD donors
- Identification of effective practices
- Opportunities for improvement in potential donors deemed medically unsuitable.
- Categorizing causes of death to be consistent across all OPOs

Summary of discussion:

Committee members asked questions about the time needed for OPO staff to complete the tool and whether the tool would be completed in real time by OPO staff or whether portions of the tool would be completed later as part of the medical record review or clinical record review. The Workgroup Chair noted that the tool in print form appears long because you cannot see the logic that would be built into it. Staff will be completing sections of the tool at different times in the potential donor evaluation process. Once you apply the logic algorithms, the staff may not be completing the entire form and drop downs will be incorporated that cannot be seen on paper. Staff are completing about two EDR screens. The tool is meant to be an outcome tool that is utilized in real time not to influence practice but rather to record what happened in the decision making throughout the donor triage process and the potential donor/donor case would not be closed until OPO staff finished completing the tool.

A Committee member noted that one of the things that has hampered the OPO community over the last decade or so is trying to create standardized definitions. This tool attempts to eliminate that need, so there are multiple data points throughout where the current staff decision making is put into the logic. The Committee member who is also a Workgroup member asked that others help identify things in the tool that are unclear or if they cannot figure out what they mean because the goal is to remove decision making by front line staff.

The Committee member asked how this data is going to be delivered to the OPTN contractor in the future and is it going to be a form like the Death Notification Record (DNR) or a Deceased Donor Registration (DDR) or will members be able to download it from their system into the OPTN Computer System. This could be a big lift for the OPO staff if they need to re-enter the data into the OPTN Computer System. The Workgroup Chair responded that this is a future discussion by the Workgroup, but non ventilated referrals make up about 98% of the referrals that an OPO gets so it is only a handful of data that OPOs would be asked to provide. OPTN contractor staff noted that the intent is that the data would be electronically transferred from the OPO electronic donor records (EDR) to the OPTN computer system. The OPTN would work with EDR providers to automate that process.

Next Steps:

The Workgroup will meet next on November 9, 2023, to review the logic maps and the data definitions. The concept paper will then be reviewed by the Workgroup at its December 1, 2023, meeting and the MPSC will review and vote on sending the concept paper out for public comment during its December 6, 2023, meeting.

10. Expeditious Task Force: Organ Usage through Placement Efficiency

The OPTN Vice President, who is an advisor to the task force, provided an update on the rationale for the Board's creation of the Expeditious task force. He noted the OPTN had recent success in implementing allocation changes that improved equity in transplantation. He also noted that increased offer volume and rising non-utilization of deceased donor kidneys are stressing the donation and

transplantation system. The Board desired to create a group within the donation and transplantation community to improve efficiency, while maintaining the recent equity gains.

Two MPSC members who are also members of the task force described their experience serving on the task force so far.

Staff provided the Committee with an update on the Expeditious task force, including:

- details regarding the number of patients, OPO and transplant hospital representatives appointed to the task force,
- a summary of activities from the task force's first in-person workshop,
- ongoing activities, and
- plans for additional workshops and updates to the OPTN Board of Directors.

Staff noted that the task force's work is expected to include Plan-Do-Study-Act (PDSA) or similar quality improvement initiatives, especially regarding allocation out of sequence and expedited placement efforts. Staff are drafting a proposal for Executive Committee consideration that will revise OPTN bylaws and establish a framework for shorter, PDSA style variances conducted as a part of the task force work. Anticipating that allocation activities associated with approved variances in the future will not require MPSC review, MPSC leadership asked for this topic to be brought to the MPSC for discussion. Specifically, the MPSC was asked the following questions:

- What does the MPSC like about the opportunity for variances to support allocation PDSAs?
- What concerns does the MPSC have about the approach?
- What suggestions does the MPSC have for creation, approval, and evaluation of allocation PDSAs?
- What are some scenarios the MPSC recommend be tested through allocation PDSAs?

A committee member asked which entity will be responsible for reviewing the results of the PDSAs? Staff noted aggregate data will be publicly available to everyone and that the framework is still being established for which entity or committee will review individual variance information. The committee member requested the MPSC review member-level data. Later, the same committee member asked how many OPOs may participate in PDSAs, noting geographic variability. Staff explained that question has not been answered yet, but part of the PDSA is to evaluate processes to see whether they can be spread nationally and to different geographic regions.

Another committee member noted that variances must not result in OPOs routinely allocating out of sequence to a particular local transplant program and bypassing other nearby programs with sicker patients.

Later, a different committee member noted that in instances of a late decline, such as a transplant program turning down a liver offer in the donor operating room, the only realistic way to place the liver is likely to ask a transplant program that is nearby to come and visualize the liver; it is unrealistic to suggest the liver can be packaged and then allocated to a program farther away. The same committee member also noted that it is in the interest of patients for all organs to be utilized.

A third committee member expressed support for utilizing PDSAs and noted many organizations are already using this approach to improve their own practices. She asked whether the PDSAs would be programmed into the OPTN computer system and noted the importance of ensuring the impact of PDSAs on the workforce. She also suggested that only PDSAs with some potential for national spread should be tested. Staff noted those aspects are valuable and can inform a decision matrix that can be used to select which PDSAs to test.

A different committee member expressed support for the initiative and noted it would be helpful to better understand the objectives and how "efficiency" is defined, such as improvements to time or cost. He requested the creation of efficiency-specific metrics to help define and measure the efficiency and success of this work.

A committee member asked that PDSAs focus on hard-to-place organs and reducing the time from offer to acceptance, since greater cold ischemia time decreased the likelihood of organ acceptance.

Committee members and staff discussed the importance of closely monitoring all PDSAs to ensure there are no decreases in equity or access; gains in efficiency cannot come at the expense of recent improvements in equity.

Staff asked transplant program representatives on the MPSC what situations the task force may need to consider to encourage transplant programs to accept more offers that they receive.

A committee member answered that logistics and transportation are significant factors in his hospital's ability to accept kidneys, and perfusion opportunities is an important factor for non-renal organs. He also noted that earlier identification of which programs are likely to accept an expedited offer and making that offer faster are critical to successful placement efforts. He expressed support for the efforts to minimize the number of offers to programs that are not likely to accept them to improve the system overall. Later, another committee member noted that perfusion of kidneys, at least during allocation, significantly increased her program's ability to accept kidney offers.

Another committee member noted the need for increased patient-level offer filters because the compatibility of the potential donor and recipient is a significant factor in whether they can accept an organ offer, specifically for heart patients.

The committee continued to discuss the impact of offer filters on efficiency of the system and expressed support for filters as a necessary tool to minimize inefficient work. They discussed the different values and need for program level and patient level filters.

One committee member suggested program-level filters do not work as well as patient-level filters for kidney programs. Another committee member agreed that patient level filters need to be improved to significantly improve efficiency of the system, by removing many of the offers received that programs know they will never accept. The same committee member noted that the community will need to provide input on the types of patient specific filters they would want, and that each organ type will likely need different filters.

A different committee member indicated she believes program level filters can work well but need to be updated to reflect known selection practices. For example, the system currently only allows liver program to select a single age cut off, even though the program has different age requirements for brain dead donors and donors eligible for donation after cardiac death. As a result, her program is unable to screen off offers she knows she will not take from donation after circulatory death donors. Furthermore, the OPO is still required to make those offers and wait for a response from her program before the OPO can allocate to other programs known to accept those offers.

Lastly, she indicated that more reliable data regarding kidney biopsies, specifically by having nephropathologists read the biopsies, would be helpful in allowing her to accept more kidney offers.

11. Report of Investigative Activities

OPTN Contractor staff presented a summary of investigative activity from September 2023. The report included the number of reports staff received, modes of receipt, reporting and subject, member type, general classification of the issue, and how many cases staff referred to the MPSC, closed without

sending to the MPSC, or are still actively investigating. Much of the presentation focused on reports that staff did not refer to the full MPSC for review, and the reasons why. Reasons for non-referral included an inability to substantiate the claim, lack of patient safety issue or policy noncompliance.

The Committee asked to see more information on one closed report, which was reviewed and discussed in closed session.

12. MPSC Brainstorming: FDA Oversight of Perfusion Devices

HRSA has requested a joint meeting between the MPSC, the OPTN Operations and Safety Committee (OSC), and the Food and Drug Administration (FDA) to discuss the oversight of perfusion devices used for transplantation. The purpose of this meeting is to discuss FDA and OPTN oversight on these devices and consider where, if any, overlap may occur and how the two entities can best work together on this issue. HRSA has asked for the MPSC and OSC to brainstorm questions for the FDA prior to their meeting, which has yet to be scheduled.

Summary of discussion:

Committee members are interested in where FDA oversight ends and where OPTN oversight begins. The member noted that while the FDA has purview over the device, the MPSC needs clarity on how to handle issues that arise related to chain of custody or vendor service issues that are not inherently caused by the functionality of the device. Members assume that if the device functions properly, but a procedural failure occurs, that the FDA would not be engaged in this safety consideration. However, as non-OPTN members it is not currently possible to hold the vendor of the device accountable for procedural or behavioral shortcomings.

Since the MPSC is discussing engagement with non-OPTN members, they highlighted the shortcomings of the bylaws which exclude these specific groups from OPTN oversight. Currently, the OPTN member is liable for the actions of the contracted servicer and what steps have been taken between these OPTN member and non-OPTN member to address the issue. A member noted the ever-changing technology and that it could be a challenge to include each of these companies as an OPTN member. A member recommended including these players as part of the membership bylaw revision and differentiated the role between product providers and service providers. Members have mixed feelings about the role of non-OPTN members and how to integrate and hold them accountable.

A member inquired if post-approval monitoring and data is available for MPSC review and the outcomes of reporting. Members highlighted the challenge of finding some of the information they are looking for on the FDA website. However, members agreed that regardless it is essential to report any information that would be relevant for the FDA to know even if it is challenging to access or obtain that information. A member highlighted the challenges the heart community has experienced with FDA devices and working through the recall process.

A HRSA representative noted that they became aware of some concerns of potential devices malfunctions during OPTN Committee meetings and brought these concerns to the attention of their leadership and the FDA. As a result, HRSA has requested a meeting with the OPTN MPSC and Operations and Safety Committees and is open to providing presentations to any other OPTN Committee that would find this information valuable. Members noted that it is imperative that they use their expertise in transplant as a resource for the FDA since transplant-specific activities are just a small component of the total FDA oversight.

A member recommended developing a document that crosswalks between the FDA and OPTN oversight as a useful resource for all transplant members to use. A member identified the transplant process as

the component that the OPTN has oversight of and should build out expectations and requirements for how those processes should occur.

13. Membership Bylaw Revisions

Staff provided an overview of the MPSC's Membership Requirements Revisions project, which is being restarted after being placed on hold. The project was established in July 2019 as a top priority that responded to Task 3.6.4 of the OPTN Contract to develop a process for a reassessment of membership status. At that time, the committee chose to also conduct a comprehensive review of all membership requirements for currency and consistency. The MPSC had developed a bylaw proposal for revisions to Appendix A: *Application and Review Process*, Appendix B: *OPO Requirements*, and Appendix D: *Transplant Hospital Requirements* as well as a framework for revisions to the organ specific program requirements before the project was placed on hold pending HRSA and HHS counsel review. Recently the OPTN was informed that the Membership Requirements Revision project could proceed. A plan for moving forward with the project is under development. Staff anticipates further discussion about the project as part of a prioritization exercise during the January 2024 meeting.

14. Modify Waiting Time for Candidates by Race inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations Compliance Update

OPTN Staff presented current progress for the eGFR waiting time modification project and the status of the membership regarding coming into compliance with the project. Feedback was requested regarding a possible expedited review process by the MPSC after the deadline of January 4th.

Summary of Discussion:

This project is a high priority for OPTN leadership and the MPSC. A member observed that their transplant hospital has undergone review of their Waitlist but have not yet sent in their attestation so that they can send in modifications through the end of the year. This was noted as a communication opportunity as the attestation can be sent in if the hospital's Waitlist has been fully reviewed but modifications can still be made as recipients are added to the Waitlist. A main concern at this time is the hospitals that have not yet begun reviewing their Waitlist given the amount of work required to complete this task and come into compliance. A member noted that many hospitals remaining are pediatric programs which have never utilized race in eGFR calculations, however they are still required to send in attestations.

Members discussed that upcoming communications with hospitals regarding the eGFR project should emphasize the high priority nature and that the MPSC will begin immediate review of hospitals that have not submitted attestations by the deadline. The Vice-Chair stated that an additional MPSC meeting is likely going to be needed just to review this issue and members should begin considering what the appropriate action would be on a case-by-case basis. The MPSC would likely view a hospital that began reviewing their Waitlist several months prior to the deadline but was unable to complete the work in time in a different light to one that did not begin at all.

A HRSA representative remarked that this project is also a high priority for them and suggested that the MSPC make it clear that they will consider all recourse for non-compliance up to and including public adverse action. It was also suggested that a firm timeline be established for MSPC review and response to non-compliance. MSPC members discussed sending a letter to transplant programs in conjunction with HRSA, HHS, or CMS to underline the importance of completing this project. The Vice-Chair specified that inquiries will be sent immediately after the deadline with an expected response time of one week, followed by swift MSPC review, and that all actions will be considered on a case-by-case basis.

15. MPSC Education/Communication Initiatives and Policy Referrals

An OPTN staff member 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 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 Committees for suggested work.

Update on MPSC 2022 MPSC Recommendations

Staff updated the committee on two recommendations that were established by the MPSC in 2022. These included:

- Recommendation to OPO Committee to address late turndowns and non-utilization due to duplicate acceptances.
    - This proposal is titled 'Modify Organ Acceptance Limit' and will be going to the OPTN Board of Directors for approval in December 2023.
- Recommendation to the Ad hoc Disease Transmission Advisory Committee (DTAC) to clarify HIV results.
    - The DTAC has worked with the Centers for Disease Control and Prevention (CDC), FDA, and National Institutes of Health (NIH) on testing guidance for considering if the HIV Organ Policy Equity (HOPE) Act requirements apply to donors with one positive HIV test result or a clinical determination based on all available tests. This work helps to distinguish if a donor is HIV positive or HIV infected and how the organ must be allocated. The DTAC released a concept paper for public comment during the Summer 2023 cycle.

Status of Policy Referrals

Staff explained that since the process was formalized, six policy referrals have been sent to other committees. These referrals include:

- Standardize Reporting Information to Patient Safety Contacts (referred to DTAC). A policy proposal is slated for Winter 2024 public comment.
- Clarify Requirements for Reporting Post-Transplant Diseases (referred to DTAC). The DTAC plans to undertake this work once the Patient Safety Contact project is finalized for public comment.
- Review Prohibited Vessel Storage Policies (referred to DTAC). The DTAC and the OSC are jointly interested in permitting the storage of HCV+ vessels, however, in order to do so the 2020 Public Health Service (PHS) Guideline would need to be revised by the CDC. The CDC is not supportive of this work now and is unwilling to modify the PHS Guideline to permit this change in policy.
- Create a Centralized Vessel Storage Reporting Mechanism (referred to the OSC). The OSC is planning to develop a concept paper for the Summer 2024 public comment cycle. Their goal is to better understand the challenges of the transplant community and modify vessel policy in a collaborative fashion.

- Align Organ Packaging Labels with OPTN Policy Requirements (referred to the OSC). The OSC is exploring opportunities to align the labels without a policy change.
- Consider Clarifying DCD Conflict of Interest Policies (referred to the OPO committee). A policy proposal is slated for Winter 2024 public comment.

Potential Policy Referral

Staff discussed two potential policy referrals with the Committee. First, the MPSC discussed transportation events, which the Committee had voted to remove from the Require Reporting of Patient Safety Events during the October 16 MPSC meeting.[1] During that meeting, the MPSC voted on the final proposal language and decided to keep "an organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ" and "the incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ." However, the MPSC voted to remove "an organ did not arrive when expected and resulted in the intended candidate not receiving a transplant from the intended donor because of the transportation issue" and refer it to another OPTN Committee.

The MPSC discussed what the issue is, how it could be addressed, which Committee should address it, and the urgency of the referral:

- A member noted that the Patient Safety Portal and the MPSC are not the correct bodies to receive this information, but that it is important information to collect, which is why it would be more appropriate for a policy referral.
- Members recommended referring this to the Operations and Safety Committee (OSC)and the Data Advisory Committee (DAC) for a collaborative data collection project.
- Members had mixed opinions on urgency, noting that media attention on travel issues could make it a high priority, but others recommended moderate priority due to the limitations in the existing data available to inform the decision. Members ultimately agreed on moderate to high priority.

The next potential policy referral arose through a case submitted through the patient safety portal where a transplant hospital procurement team traveled to the host OPO to conduct the recovery and brought expired medication. The OPO identified and disposed of the expired medication as required by OPTN Policy 2.2 *OPO Responsibilities*. In this case, everything was done correctly by the OPO, and the transplant hospital modified its process to prevent this instance from recurring, but with the change in how procurement is occurring, staff wanted the MPSC to consider if the responsibilities of OPOs were evolving. Staff also highlighted that procurement communication and best practices have been highlighted in previous MPSC Chair emails, but this remains a recurring theme in Patient Safety Portal submissions. Staff solicited feedback on whether the changes in recovery practices required policy to shift the responsibility from OPOs and onto those conducting the recovery or if additional education would help address these challenges.

- A member highlighted the challenge of conducting organ recoveries in the early hours of the morning when teams are not fully staffed or working at their highest capacity, which lead to dealing with the situation at hand as opposed to reviewing, modifying, and improving the

[1]OPTN Membership and Professional Standards Committee, *Meeting Summary*, October 16, 2023. https://optn.transplant.hrsa.gov/media/1arnoe1z/20231016_mpsc_meeting_minutes_public.pdf

challenges the teams are facing. The member recommended having a separate group, whether a workgroup or different Committee, to address this issue in a holistic manner.

  - A member agreed that procurements continue to be a challenge for both abdominal and thoracic procurements.

- A member noted that our current policy identifies procurement as the responsibility of the host OPO, regardless of whether a transplant team is conducting the recovery, or a third-party vendor is utilized. The member cautioned that shifting responsibility from the OPO to other members could cause confusion where no one party is responsible or there is a constantly shifting dynamic. The member recommended a workgroup or forum of individuals who conduct procurements to address this issue more appropriately.
- Circling back to the main issue, a member stated that it is the procurement team's responsibility to ensure that their supplies are unexpired and appropriate to ensure a safe recovery occurs. The onus is on the procurement team to bring the correct supplies, and the OPO can review and validate their materials, but when the procurement team is unprepared then added challenges and delays arise that impact the efficiency and success for the procurement.
  - Currently, policy relies on the OPO to be responsible for the actions of a procurement regardless of whether they are the actions of the OPO or the transplant hospital procurement team.
  - A member stated that what occurs in the OR is the responsibility of the OPO, but that the transplant hospital should be expected to maintain the appropriate items needed for procurement. The member recommended a conference call between the OPO and procurement team prior to travel and identifying a lead surgeon.
- A member noted that with the involvement of third-party vendors, it is possible they could bring expired medication to the OR, but as a non-OPTN member they would not be responsible by policy, therefore further complicating the issue.
- A member noted that although it may be easier to say that the OPO is responsible, the OPO does not have the ability to change or influence the systems in place at the transplant hospital to ensure that right steps are being taken for procurement teams.
- A member suggested that in the short term, community education would be beneficial and potentially using the Patient Safety Contact as a resource. The Committee agreed that education would be beneficial in the short term, but additional discussions will need to be had to better understand how to holistically address this in the long term.

<u>Additional Policy Referrals</u>

The Committee discussed additional policy referrals, which included:

- Patient-specific donor acceptance criteria, specifically age of donor and distinction between DCD and DBD.
  - The Network Operations Oversight Committee may be able to prioritize this and consider the possibility of system enhancements that could fulfil this request.
  - The Operations and Safety Committee could be an alternative approach, but some organ specific Committee's may have their own interest in additional, specific data collection.
- Center-wide offer filters for all organ types.
  - The Lung Committee has begun working on what additional data they would be interested in collecting to include in the offer filters.

Ongoing Educational Efforts

Staff updated the Committee about ongoing educational efforts, specifically the MPSC-related presentations given at the Transplant Quality Institute (TQI) and the feedback they received. TQI attendees voiced appreciation for the MPSC Chair emails and the MPSC resource page on the OPTN website. Attendees requested more information from the Committee on the process for reports submitted through the Patient Safety Portal and trends in safety events. TQI attendees also requested resource documentation to use for ABO verification for living donors. Staff also provided information about future educational efforts at conferences in 2024. Committee members are encouraged to reach out if they would like to participate in any of these educational efforts or presentations on behalf of the MPSC.

Email Communication

Over the past 11 months, the MPSC Chair has sent out three informative emails based on topics that arose at the MPSC in person meeting as areas that the transplant community needed additional communication on. This allows for greater transparency with the community and the opportunity to send notifications about potential issues in a more expediated manner. Staff compiled a list of topics based on the content of the meeting and members were supportive of these topics with no additional feedback:

- The upcoming eGFR waiting time modification and attestation deadline and MPSC action for noncompliant programs.
- Highlight the best practices for marking kidney laterality and pre-packing confirmation of kidney laterality.
- Reminder that the OPTN member who contracts with a third-party vendor is responsible for the actions of that vendor and are expected to self-report to the Patient Safety Portal when appropriate.
- Emphasize the responsibility of the host OPO when transplant program procurement teams attend for recovery and highlight the importance of ensuring appropriate materials (medication, flush solution, etc.) are provided and expectations are communicated.

Upcoming Meetings

- December 6, 2023, 2-4:00pm, ET, Conference Call
- January 19, 2024, 2-4pm, ET, Conference Call
- March 5-7, 2024, Detroit,
- July 23-25, 2024, Detroit, MI

Attendance

- **Committee Members**
  - Maher Baz*
  - Alan Betensley
  - Kristine Browning
  - Anil Chandraker*
  - Hannah Copeland
  - Robert Fontana
  - Rich Formica
  - Roshan George
  - Darla Granger
  - Dipankar Gupta
  - Shelley Hall
  - Robert Harland
  - Rich Hasz
  - Kyle Herber
  - Victoria Hunter
  - Michelle James
  - Peter Kennealey
  - Catherine Kling
  - Peter Lalli
  - Raymond Lee*
  - Carolyn Light*
  - Scott Lindberg
  - Melinda Locklear
  - Maricar Malinas
  - Amit Mathur
  - Deborah McRann
  - Nancy Metzler
  - Saeed Mohammad
  - Regina Palke
  - Malay Shah
  - Zoe Stewart Lewis*
  - J. David Vega
  - Mark Wakefield
  - Candy Wells
  - James Yun*
- **HRSA Representatives**
  - Jim Bowman*
  - Shannon Dunne*
  - Marilyn Levi*
  - Chris McLaughlin*
  - Arjun Naik*
  - Kala Rochelle*

- **SRTR Staff**
  - Ryutaro Hirose*
  - Jonathan Miller*
  - Jon Snyder
- **UNOS Staff**
  - Anne Ailor*
  - Robert Albertson
  - Stephanie Anderson
  - Sally Aungier
  - Dawn Beasley*
  - Matt Belton
  - Dawn Bitler*
  - Tory Boffo*
  - Kate Breitbeil*
  - Tyrone Brown*
  - Jadia Bruckner*
  - Elinor Carmona*
  - Tommie Dawson*
  - Robyn DiSalvo*
  - Liz Friddell*
  - Jasmine Gaines*
  - Shavon Goodwyn*
  - Caroline Hales*
  - Asia Harden
  - Madeline Holder*
  - Houlder Hudgins*
  - Courtney Jett*
  - Elias Khalil*
  - Lee Ann Kontos*
  - Krissy Laurie
  - Ann-Marie Leary
  - Carlos Martinez*
  - Jon McCue
  - Amy Minkler*
  - Sara Moriarty*
  - Delaney Nilles
  - Samantha Noreen
  - Jacqui O'Keefe
  - Rob Patterson*
  - Michelle Rabold*
  - Shawn Richman
  - Liz Robbins Callahan
  - Melissa Santos
  - Logan Saxer*
  - Laura Schmitt
  - Sharon Shepherd
  - Courtney Skeen*

- Tynisha Smith*
- Chris Stadolnik*
- Michael Stanley*
- Sarah Stevenson*
- Juanita Street*
- Stephon Thelwell
- Marta Waris*
- Betsy Warnick
- Trevi Wilson*
- Claudia Woisard*
- Emily Womble
- Karen Wooten*
- Amanda Young*

- **Other Attendees**
  - John Lunz*

* Attended virtually