OPTN Membership and Professional Standards Committee (MPSC)
Meeting Summary
October 26-27, 2022
Chicago, Illinois

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Introduction

The Membership and Professional Standards Committee (MPSC) met in-person in Chicago, Illinois, and via Citrix GoToTraining in both open and closed session on October 26-27, 2022. The following agenda items were discussed during the meeting:

1. NASEM Report - Discussion of MPSC-related recommendations
2. Senate Finance Committee Report - Discussion of Implications to OPTN Peer Review
3. MPSC Operational Rules – Open Session
4. Report of Investigative Activity
5. Wakefield Criteria and Required Member Reports to the OPTN
6. Monitoring Descriptions and Plans for New Policies
7. Membership Bylaws Proposed Corrections
8. Performance Monitoring Enhancement (PME) Project - Ongoing Implementation Activities
9. Educational Initiatives

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

1. NASEM Report - Discussion of MPSC-related recommendations

Staff provided a high level overview of the recommendations contained in the National Academy of Science, Engineering and Medicine (NASEM) Ad Hoc Committee on A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation and Distribution report on "Realizing the Promise of Equity in the Organ Transplantation System" issued in February 2022. The Committee was provided a summary of the ongoing and upcoming OPTN work that aligns with the NASEM recommendations, as well as the current MPSC projects and past project ideas. As requested by the Policy Oversight Committee (POC), the Committee discussed suggestions for projects that the MPSC or another committee could do that align with the NASEM recommendations.

A Committee member suggested that a better understanding of the organ specific data would be helpful in formulating recommendations regarding the balancing of equity versus survival measures. Data would help determine the priority of competing goals including access, equity, earlier transplants, survival, or more aggressive transplants in the elderly population. The Chair noted this is one of the challenges in considering projects since there are many objectives within the NASEM report and improvement in one area may negatively impact another. For example, if the focus is on improving equity, an equity initiative may unintentionally result in more difficulty utilizing harder to place organs. If the focus is on increasing organ utilization by moving harder to place organs to urban aggressive transplant programs, another disparity may be created by making it harder for rural patients to have access. There are often unintended consequences even when a policy is created with the best of intentions.

A number of Committee members noted that, in order to effectively make many of the changes recommended in the NASEM report, the OPTN would need to bring payers, the Centers for Medicare and Medicaid Services (CMS) and insurance companies, to the table to be part of the discussion and collaborate in potential changes. Specifically, one Committee member noted that if a national dashboard of standardized metrics is created, as recommended in the NASEM report, there will need to be performance-based reimbursement associated with meeting those metrics.

A Committee member suggested that the OPTN determine a single moon shot statement or goal such as no waiting list deaths or no waiting time and establish projects that cascade up to that goal.

A Committee member, who is a transplant recipient in addition to a transplant professional, acknowledged that the NASEM committee decided not to address living donation. However, as a recipient of a living donor transplant, he suggested consideration of efforts to encourage living donation, noting that the kidney waiting list could potentially be eliminated through living donation.

A significant portion of the Committee's discussion centered on member performance metrics in line with NASEM recommendation number 1 to develop national performance goals for the U.S. organ transplantation system.

- A number of Committee members suggested a project to evaluate OPO performance monitoring and develop new OPO performance metrics. An OPO performance monitoring project would align with NASEM recommendations 1) Develop national performance goals for the U.S. organ transplantation system and 12) Create a dashboard of standardized metrics to track performance and evaluate results in the U.S. organ transplantation system. One member noted that use of the "eligible" definition has limited potential for expansion of available donors and does not adequately measure OPO growth and performance. One member suggested setting a national goal of a certain number of organ donors per 100,000 population annually. OPO and transplant hospital performance metrics should be developed to further that national goal. The member suggested a national goal could be determined through an examination of current practice at high performers, as well as an examination of improvement opportunities at low performers.
- Committee members discussed evaluating a measure of longer term outcomes both on a systems level and at the program level noting that the U.S. long term outcomes are below those of other countries. A member noted that lower long term outcomes are potentially a result of the system's current focus on one to three year outcomes. Patients are followed closely during the early post-transplant period while not receiving as much expert care after that period. Another member noted that lack of compensation for following patients longer term contributes as well.
- A Committee member opined that weighting performance metrics that evaluate all phases of transplant program care equally can raise issues because the incentives created by the metrics do not always align. He suggested that the metrics should be balanced in a way that reflects the transplant system's top priority.
- Some Committee members suggested consideration of a post-transplant outcomes carve-out or variance for transplants using donor organs that are higher risk could encourage programs to accept and use these donor organs by alleviating their concern about consequences related to post-transplant outcomes. Some noted that these strategies would only be effective if adopted by the Scientific Registry of Transplant Recipients (SRTR) for public reporting used by insurance

companies in addition to changes to the MPSC review process. Committee members suggested several potential alternatives to consider:

- Carving out of all transplants using higher risk donor organs from consideration, potentially using SRTR data on harder to place organs to develop carve-out criteria;
- Dividing post-transplant outcomes into buckets of higher risk and lower risk transplants while continuing to review outliers in both buckets so that programs and MPSC could identify areas where survival is lower than expected;
- Carving-out those transplants where programs are using innovative approaches to use organs not currently being transplanted for review on a national level rather than by individual hospital;
- Excluding dual kidneys since only a fraction of the programs that indicate they will use dual kidneys actually do accept them currently.

Others expressed concern with use of a carve out for post-transplant outcomes noting that:

- Programs can be aggressive and still have very good outcomes under the risk adjustment model;
- Some programs may be adversely affected by a carve-out so we need to review data carefully and examine the effect of a carve-out before moving forward;
- People often express concerns that poor outcomes in higher risk transplants will result in lower SRTR ratings when in fact, with risk adjustment, poor outcomes in lower risk transplants are generally what causes poorer ratings.

A Committee member suggested evaluating the level of transplant program aggressiveness under the previous post-transplant outcomes threshold, the current post-transplant outcomes threshold, and potentially moving the post-transplant outcomes threshold even higher to test whether programs become more aggressive when post-transplant outcomes expectations are changed. Another Committee member opined that if the threshold was raised, we would limit the Committee's ability to see patterns of events that might be a one off event for a particular hospital. Our reviews provide the opportunity to identify patterns of behavior or characteristics of donors or recipients that have a pattern of resulting in poor outcomes.

- A Committee member noted that some risk averse behavior is based on a lack of understanding of risk adjustment and further education is necessary. He suggested a project to provide programs with data that stratifies patients showing how they are doing with their higher risk donor organs and recipients. He noted that being able to review that stratified data may instill more confidence in programs to accept these organs and perform these transplants. The chair suggested that programs can use the worksheets on the SRTR secure site to evaluate the effect of certain donor and recipient characteristics on their post-transplant outcomes. However, another Committee member noted that use of those tools requires expertise, time, and effort so many programs do not use them. An SRTR representative acknowledged that use of the SRTR worksheets does take time and effort and he would pass on the feedback that a more user friendly tool would be helpful.

A Committee member suggested looking at opportunities to reward transplant programs for evaluating and improving equity within their programs. In addition, he suggested gathering information for

dissemination about practices and programs geared towards ensuring access to disadvantaged patient populations. The Chair noted that some in the community have discussed evaluating whether transplant hospitals are serving their local population, for example by looking at data on whether the number of black candidates on their waiting lists is proportional to the black population in the local area.

A number of Committee members also suggested efforts to support quality improvement. The Chair suggested a project to expand the system to effectively sharing MPSC findings and never events with the community so transplant hospitals and OPOs can prevent these events from happening again. She acknowledged the concern for confidentiality of the peer review process but noted that broader sharing of the factors related to never events could prevent similar events at other member institutions. This project would align with NASEM recommendation 13) Embed continuous quality improvement efforts across the fabric of the U.S. organ transplantation system, as well as some of the concerns of the Senate Finance Committee. Committee members suggested publishing papers on the topics related to the work of the MPSC and disseminating information about effective practices that could optimize utilization of donor organs that are not currently being utilized.

A Committee member suggested a focus on specific standardized allocation strategies to preemptively get hard to place organs to transplant programs that will use them and to support rescue efforts for declined organs to decrease cold ischemic times in order to reduce the organ non-utilization rate. She explained that strategies are needed to get these organs to programs that will accept and transplant them in alignment with the NASEM theme of underuse of procured organs and recommendation 9) to make it easier for transplant hospitals to say "yes" to organ offers. The Chair noted that one of the challenges when trying to determine what to focus on is a recognition that we all support the use of more organs but then we naturally tend to default to discussions of how to get those harder to place organs to current aggressive programs that will use them. However, we must remain aware that some programs are better able than others to say yes for a variety of reasons such as being located in a metropolitan area or having an airport that can get kidneys to a program more quickly. When considering strategies for decreasing non-utilization, we must evaluate whether those changes create a new inequity by defaulting to diverting a large number of organs to large aggressive programs.

A Committee member encouraged involvement of the Pediatric Transplantation Committee in efforts that result from the recommendations in the NASEM report to evaluate how changes in priorities could impact children. She noted that often when the focus is on increasing volume and numbers, pediatric patients can be disadvantaged.

One Committee member suggested a re-evaluation of the use of the Kidney Donor Profile Index (KDPI) in allocation, noting that giving each kidney an individual number, particularly in the higher KDPI ranges, rather than a general category appears to have a negative effect on kidney utilization.

A couple of Committee members expressed disagreement with the recommendation to prioritize patients on dialysis noting this would have a negative effect on pre-emptive transplant referrals and noted an inconsistency of this recommendation with other recommendations in the report and with the CMS recommendations and Executive Order that encourage more pre-dialysis referrals and pre-emptive kidney transplants.

A Committee member suggested a pilot project to investigate newer techniques for predicting whether a particular organ will be rejected, other than ABDR mismatching, to see whether outcomes could improve by using some of these available new techniques. He referenced current work at NYU and suggested that the Histocompatibility Committee could pursue this project.

In summary, MPSC members suggested the following project ideas to be pursued by the MPSC:

- OPO performance monitoring – Evaluate the use of different metrics for monitoring OPO performance, potentially choosing metrics based on whether the metrics will effectively support meeting an established overall goal of X organs donated/100,000 population. In addition, the MPSC should support quality improvement by gathering and publishing effective OPO practices.
- Transplant program performance monitoring – Evaluate the use of longer term post-transplant outcomes metrics either system-wide or for individual programs and buckets or carve-outs for higher risk transplants to encourage use of harder to place organs. Evaluate balancing new metrics in a way that supports top priorities and provide more education on risk adjustment and the characteristics of programs' outcomes that result in program being identified for review. These efforts can be incorporated into existing Transplant Program Performance Monitoring Enhancement project.
- Right organ to the right patient – Develop specific standardized allocation strategies to preemptively get hard to place organs to programs that will use them and to support rescue efforts to decrease cold ischemic times to reduce the organ non-utilization rate. When developing these strategies, need to evaluate if the proposed strategies will result in a new inequity. These issues will be addressed in the existing MPSC project on allocation review.
- Support quality improvement by expanding a system to effectively share MPSC findings and never events so that other hospitals and OPOs can truly learn and prevent these events from happening again. This could be accomplished through publication by MPSC members as well as the use of educational tools.

The MPSC also developed ideas for consideration by other committees:

- Reward programs for evaluating and improving their performance from an equity stand point; gather practices and programs geared toward ensuring access to disadvantaged patient populations; and potentially provide information on whether transplant hospitals are adequately serving their local population such as evaluating whether programs' waiting lists reflect their local population.
- Re-evaluation of the use of individual KDPI scores for use in allocation based on concern that giving each kidney an individual number, particularly in the higher KDPI ranges, rather than a general category appears to have a negative effect on kidney utilization.
- Histocompatibility Committee could pilot use of new techniques to predict organ rejection, other than ABDR mismatching, to see whether outcomes could improve by using some of these available new techniques. He referenced current work at NYU.
- Efforts to encourage living donation since the kidney waiting list could potentially be eliminated through use of living donation.

2. Senate Finance Committee Report - Discussion of Implications to OPTN Peer Review

The MPSC discussed the potential impact of the release of MPSC information within the Senate Finance Report, as well as criticisms regarding the effectiveness and transparency of the current oversight system.

Impact of Disclosure of Peer Reviewed Information

The Committee expressed significant concerns about the public disclosure of peer review information shared with the U.S. Senate Committee on Finance and the impact it may have on OPTN members' willingness to participate in reviews with the MPSC. While the Committee noted that peer review

protections are not absolute, that certain MPSC-related information has been shared in response to subpoenas in the past, and that no one can prevent the disclosure of information from any entity with a legal right to the information, the release of information as a result of the Senate Committee on Finance hearing report was the largest public release of information typically considered protected by the peer review process. Consequently, the MPSC understands why some members may be reluctant to share information with the Committee in the future out of fear of public disclosure. At the same time, the MPSC noted member engagement and transparency are crucial elements of an effective peer review process, and that the OPTN Bylaws, Appendix L, Section 5 requires OPTN members to respond to all requests for information associated with investigations into a potential noncompliance with OPTN obligations. As a result, the MPSC felt strongly that all members should be expected to continue to participate in the MPSC's review process. Though the Committee has not yet encountered a situation where a member refused to provide information for review, the MPSC discussed that if a member ever did so, the Committee would consider referring the matter to the Secretary of Health and Human Services, to communicate the impact the public disclosure of MPSC information has had on the ability to thoroughly follow the peer review process. Committee members also commented that service on the MPSC is a still a valuable opportunity but were uncertain about the impact that the disclosure of MPSC information may have on the MPSC's ability to recruit future members.

Considering Alternative Review Frameworks

The Committee recognizes the importance of continuous process improvement for the OPTN, members and the MPSC itself. In that spirit, the MPSC also considered alternative reporting and review mechanisms that exist in other industries and could potentially improve safety and increase transparency, while still providing protections against the disclosure of shared information. Specifically, the MPSC evaluated recommendations that the MPSC adopt systems similar to the Aviation Safety Reporting System (ASRS) utilized by the Federal Aviation Administration (FAA), and healthcare Patient Safety Organizations (PSOs) established under the Patient Safety and Quality Improvement Act of 2005. The MPSC's review noted that information organizations report to ASRS and PSOs are never used for compliance activities, and that ASRS and PSOs are not intended to replace compliance oversight by other entities. For example, the FAA maintains robust compliance and enforcement activities that are completely separate from the ASRS, and the ASRS does not accept information on accidents or criminal activities. To ensure the separation of quality improvement and compliance processes, organizations with required reporting or that have any regulatory oversight responsibilities are not permitted to serve as a PSO; organizations that report events to a PSO are still expected to report safety events to all applicable oversight bodies.

In discussing alternative frameworks, the MPSC discussed at length the Committee's role and purpose. As noted in the Committee's proposal "Appendix L Revisions" in 2018, some of the MPSC's primary objectives are to "address potentially urgent and severe risks to patient health and public safety in a timely manner" and to "promote positive MPSC and member interactions focused on quality improvement." Similarly, in the Committee's enhancing Transplant Program Performance Metrics proposal, the Committee stated, "… the MPSC acknowledged it has a fiduciary responsibility to monitor member performance to identify potential patient safety issues. At the same time, the MPSC strives to support and collaborate with transplant programs to address performance improvement opportunities." The MPSC's charter also notes that the MPSC' "reviews events identified as presenting a risk to patient safety, public health or the integrity of the OPTN", and "evaluates and supports OPTN members by providing feedback on recommendations to improve members' performance, compliance and quality systems." In short, these are charges, responsibilities and improvement strategies all focused on best serving patients.

As part of this larger conversation, the MPSC shared its belief that it is important to differentiate between compliance and quality improvement. All compliance is quality improvement, but not all quality improvement is compliance. Within the OPTN, the MPSC is responsible for overseeing member compliance with OPTN policies and obligations. When an occurrence of noncompliance is identified, the MPSC uses quality improvement tools to help members take substantive actions to address the specific issue of concern and guide them back into compliance. Since the performance expectations and reviews are outlined in the Bylaws, the Committee's review of member performance is an OPTN compliance activity. To further strengthen this process, the MPSC believes that reporting events for purposes other than for review of imminent safety issues and member compliance (similar to the ASRS or PSO reporting structures) may be beneficial for the OPTN, particularly in instances where OPTN policies may not exist to guide member behavior. The MPSC believes an approach that would establish a reporting process focused on quality improvement but not associated with an existing OPTN compliance issue should be distinct and separate from MPSC processes. The MPSC noted an exclusive quality focus would require a significant amount of resources to effectively collect, process, and share information learned through the system; the MPSC does not have the resources to manage both processes. The MPSC also believes the separation of two systems would mirror effective practices in other industries and encourage greater participation and reporting in the quality system. The MPSC encourages the Board of Directors to consider developing a quality data and event reporting system within the OPTN.

3. MPSC Operational Rules – Open Session

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 or bylaw change or process improvement created a need to update them.

Starting this year, the Committee was asked to review all approved rules and processes annually. This is intended to increased transparency 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 follows.

<u>Overall processes</u>

- 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, including the number of cases already assigned to each reviewer. Cases are typically posted for 14 days. If all reviewers agree on the outcome of the case, the case is assigned to a consent agenda for MPSC review at an upcoming meeting. If reviewers disagree, they communicate directly to try to reach consensus, but cases with continued disagreement are discussed at a future MPSC meeting. In addition, reviewers may decide to place a case on a discussion agenda even if they agree on a recommendation, but believe the issue warrants full MPSC discussion. The discussion agenda includes cases that will result in members interacting directly with the Committee, for example through an interview. A committee member expressed support for the current process and the ability to review other reviewer comments when there is a disagreement, and 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. This process includes cases in which the MPSC has requested an interview or when an interview is offered because the Committee is considering an adverse action. 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. A Committee member asked why a member might waive an interview, and staff responded that in the past members may have felt that the recommended action was appropriate and an interview would not be a good use of MPSC or member resources. Another Committee member noted that the increase in informal discussions and decrease in interviews offered may make cases where this rule needs to be applied rare. The Committee supported continuing this process.

Performance Related

- Sending initial performance inquiries: As outlined in the OPTN Bylaws, Appendix B.2 (*OPO Performance Requirements*) and Appendix D.12 (*Additional Transplant Program Requirements*), the MPSC will conduct reviews of OPOs and transplant program performance if specific OPO and transplant program metrics meet certain thresholds. The MPSC approved an operational rule to automatically send an initial inquiry for members who are newly identified for performance review when the data is available, without a committee vote. In the past staff added all newly identified programs and OPOs to the consent agenda for the next MPSC meeting for the Committee to vote on sending the initial inquiry letters. Historically, the MPSC unanimously approved sending initial inquiries. This operational rule better aligns staff processes for performance reviews with other case types and reduces the administrative tasks required and allows staff to get information from members more quickly. 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 inactivate for one year? Is program currently under review? Has the program been released 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 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, which are typically held in February, July and October. Staff provided an example that if a member was released for functional inactivity at this October 2022 meeting, and if the member was identified for functional inactivity before the February or July 2023 meetings, then staff would not send the member an inquiry. If the member was identified before the next October 2023 meeting, then staff would send the member a new inquiry. The Committee had no concerns with continuing to use these guidelines.
- Outcomes review guidelines: Staff reported that with the implementation of the new transplant program performance metrics for post-transplant outcomes (90 day graft survival and one-year conditional on 90-day graft survival), the Committee eliminated any operational rules that went along with the previous transplant program one year patient and graft survival metrics. Previously, the MPSC used four of the five criteria described in the functional activity section

above. Specifically, the MPSC asked: Is program currently active? Has the program not been in active status for one year? Is program currently under review? Has the program been released in the last two meeting cycles? However, the MPSC did not consider whether the program received any offers or had any active candidates on the waitlist. The Committee discussed reinstating the rule about not sending a new inquiry for two cycles on outcomes reviews. Specifically, if a program is released from performance outcomes review in the last two cycles would you want to send a new inquiry on outcomes or not send an inquiry. One committee member asked for clarification of the time period; staff responded that if the member was reviewed by the MPSC and recommended to be released from outcomes review at this meeting (October 2022), staff would not send an inquiry if the January PSR or July PSR data identified them for review, during the MPSC's February or July 2023 multi-day meetings, respectively. The rule came about because the MPSC had already reviewed newer data when releasing them from review based on their plans for quality improvement and efforts they are making to improve, but the SRTR data is delayed. A committee member agreed that the MPSC should give the program time, and if there are continued issues the program will eventually be identified again. Another committee member asked whether the rule could be reassessed if a member's data became concerning, and staff emphasized that all of these operational rules operate on the premise that if there is a concern or something is out of the ordinary then staff will send the issue to the Committee anyway. One Committee member asked for clarification if this operational rule would apply to OPOs as well as transplant programs and staff confirmed that it would. The Committee voted to apply criteria 1, 2, 3, and 4 of the current functional inactivity operational rule to outcomes review with a vote of 30 Yes, 1 No, and 0 Abstain.

<u>Application Related</u>

- 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 also fails to submit a key personnel change application at least 30 days before the current key personnel departs, the item goes on the compliance consent agenda to receive a Notice of Noncompliance. Lastly, the rule states that if a member reports a change late a second time, the case is posted for reviewers. One Committee member asked for clarification if this rule applies if the second occurrence occurs 10 years later or if the first event involves two or more personnel. Staff responded that an event that involves two people at one time would be considered one occurrence. This operational rule was not created with a time period after which the rule resets, but there are other operational rules the Committee will review later do have time periods included. In those rules, the MPSC determined that a period of three years should be used when determining which cases are posted for reviewers. Additional discussion included whether the rule considered how late the notification is, whether it applies to both departures and switches where the current primary is not leaving the program, and noting that failure to notify within seven days could include failure to notify after key personnel leaves whether a

program has a qualified replacement or not. The MPSC felt that the rule should delineate very explicit conditions where no review is necessary. A Committee members asked if like other operational rules, staff have the option to escalate these cases when needed or timeframes seem extensive. Staff confirmed that is the case and that staff have brought cases to the Committee's attention when necessary. After additional information from staff on the frequency of these cases and the nuances of the different OPTN Bylaw requirements, the Committee agreed to limit this operational rule to just the following statement: If the 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 and educate the member on the late notification requirements. Any other cases will now be posted for Committee review.

- 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. MPSC members used to review every key personnel application for compliance with the bylaws, but the applications request very specific information that is designed to determine whether a proposed primary physician or surgeon meet the bylaw requirements. Staff post any application where there are questions or expert judgment is needed to determine whether the application meets bylaw requirements for MPSC review. A Committee member who used to review these packets during a previous term on the MPSC strongly agreed that this is a good rule to save time from reviewing applications that clearly meet bylaw requirements. Non-Institutional Members are required to renew their OPTN membership every two years, and renewal requirements are minimal. The Committee felt that these renewal applications can be placed directly on a consent agenda if all requirements are met. 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. Therefore, the Committee felt placing these cases on the consent agenda with a recommendation to reject the application was appropriate. A Committee member asked about the associated Bylaw, how the Committee would determine if relevant Bylaw language needed modification if they are not reviewing these cases, and the potential implications associated with rejected applications in limiting patient access to transplant. Staff responded stating these applications are still reviewed by three Committee members, who look for any trends or common themes among applications reviewed. Staff added that OPTN Members are offered several options in the case an application is rejected, such as an interview with the MPSC or submitting additional information. Additionally, if MPSC reviewers identify issues with relevant OPTN Bylaw language, based on applications reviewed, they can request the case be discussed with the full Committee. The Committee agreed to continue this process.
- Minimum 2-5 Year Period Interpretation: The Committee also discussed one OPTN Bylaw interpretation question. The clinical experience pathways for all organs require that the primary transplant surgeon perform a number of transplants or the primary transplant physician care for

a number of transplant patients over a two to five year period. At a previous MPSC meeting, staff had to ask the Committee to define exactly what a two to five year period means. The Committee supported the interpretation that requires a proposed surgeon or physician has to demonstrate that they did the requisite number of transplants or patient care over a two year period in which the surgeon or physician was employed and on-site at a designated transplant program. So the distribution of the transplants within the two years does not matter, but that the personnel were employed at the designated transplant program. After clarification that fellowship experience is a different pathway, and that the experience does not have to be in a recent time period but ANY 2-5 year period during their career, Committee members supported the current interpretation.

Compliance Related

- SET Tool Implementation and Update: The Survey Evaluation Tool (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 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 operational rule was updated by the MPSC in 2021 to evaluate the routine review and the first desk review with the SET and move forward with that recommendation. The MPSC will review any second desk review results and any reviews with serious concerns about patient safety, compliance or corrective action plans. The Committee did not have any concerns about this operational rule.
- Closing Self-Reported Issues with No Action: In 2021, to support as a part of an OPTN contract requirement for the MPSC to help develop a plan 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 RCA and CAP, and the member had no significant MPSC compliance history. Cases with patient safety concerns, member history of similar issues, inadequate responses or other circumstances are posted for MPSC reviewers. Compliance consent agendas note which cases are self-reported and staff review this information with the Committee during closed session before taking a vote. A Committee member confirmed that those cases are counted as reviewed by the MPSC. The Committee always has the option to pull a case off of the consent agenda for further review. The MPSC agreed to continue the operational rule.
- 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 not only the OPTN but also OPOs and transplant programs, if they have certain specific information about or suspicion of a potential disease transmission between a donor and recipient. Staff review late reports of potential disease transmissions to other members and to the OPTN. 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 resets every three years, since that is the time frame staff typically apply when reporting on a members "compliance history" with the MPSC. The Committee had no concerns or comments regarding this operational rule.

- 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. The first time 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 was asked if they had any concerns about the current operational rule in place and if this rule should also include a reset every three years. Committee members asked a few clarifying questions about the requirements in the Bylaws, and whether this applies to each program individually. The Committee approved continuing the rule, but did not want to include a reset time period.
- Vessel Storage: OPTN Policy 16.6.B (*Extra Vessels Use and Sharing*) prohibits members from storing extra vessels if the donor tested positive for HIV, HBV or HCV according to specified tests. The current operational rule in place includes automatically closing a member's first instance of storing prohibited vessels. Staff advise the member that the MPSC expects them to implement their corrective action plan, and that, should the member store any prohibited vessels again, staff will forward the information, including the first instance, to the MPSC for review. A Committee member noted, the potential risks associated with storing HIV, HBV and HCV vessels, if they were accidentally used in a patient and resulted in a disease transmission. While the MPSC acknowledges the potential risk, the Committee noted that the prohibition of storing these vessels may need to be reconsidered in order to increase utilization of organs and transplantation. The MPSC discussed whether the member's history of storing prohibited vessels should reset after three years, which aligns with the three year compliance history provided to the Committee during case reviews. The Committee determined to keep this rule with a three year reset.
- 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 an OPO has not reported the test results in DonorNet or has not uploaded the results to the attachments tab of DonorNet, then the OPO will receive an inquiry. 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 approved this rule with no additional concerns or comments.

<u>Including Historical Actions in Staff Summaries</u>:

Staff explained the purpose for including historical actions in the staff summary of case reviews. The historical action provides committee members with a description of the way the MPSC previously voted

on similar cases. Staff originally included this information to increase consistency in MPSC decision making. Case reviewers often agree with the action, but may make a different recommendation based on specific circumstances of the case. Staff encourage reviewers to review specific details of the case and provide a chosen action, comments, and feedback for the member. Over the past two years, reviewers have disagreed with historical actions between fifteen and twenty percent of the time. This seems to indicate that reviewers read the information but feel comfortable disagreeing based on the case.

Staff asked the committee whether they find the historical action helpful or it adds confusion. Options provided to the Committee included removing the information, keeping it as is, or providing a more detailed history analyzing previous actions and the ways in which cases may differ. Providing this additional information would require additional time and effort from staff.

A committee member noted that they find the historical action information very helpful to provide context and help frame ideas about why they believe a specific case may not be in alignment with the historical action. Another committee member added that it provides guidance but did not overly influence their decisions. They did not feel like a more detailed history is necessary, although one member mentioned that a more detailed history may be beneficial to remain aligned with decisions made by previous committees. Multiple committee members agreed that the historical actions were helpful. Staff concluded that they will continue to provide historical actions in the staff summaries and will consider adding relevant details in discussion items, especially those involving policies with varied voting history.

Report of Investigative Activity

Staff provided a report of all events received by the Patient Safety team from August-September 2022. The report included the number of reports, the modes of receipt, reporter types, subjects, and event types. The report also included data on the percentage of reports referred to the MPSC, not referred, or pending, and how many of the reports were substantiated or unsubstantiated.

The bulk of the presentation focused on reports that staff did not refer to the full MPSC for review and action, and the reasons those reports were not referred. Reasons for not referring included prior review by MPSC leadership and/or HRSA, the report being unsubstantiated, and a lack of policy noncompliance or obvious patient safety issue.

Staff asked the committee if there were any cases about which they would like more information, the format and frequency of the report they would prefer, and to consider any potential referrals for policy revisions or creation.

A committee member stated that the presentation format as presented was acceptable, and that the committee should review it monthly. Another committee member agreed that the report was helpful in its current format and offered a suggestion for a specific MPSC focus. A committee member asked staff about what feedback staff provided back to the reporter, particularly when the OPTN may not have purview over the issue, and staff explained that investigative staff educate the reporter in those instances. The same member offered suggestions for considering a different approach for events that are not policy noncompliances, but offering feedback to members. Answering another committee member's question, staff considered the possibility of sharing de-identified data with other committees. Multiple members agreed that getting surgical damage information back to the recovery surgeon is important. A committee member suggested unsubstantiated reports could be reported twice a year and expressed concern that upticks in staffing issues, flight delays, OR delays, etc. could result in in a sizeable increase reports and the MPSC may need to reconsider the cadence. Referencing an earlier statement that staff contact reporters, another committee member suggested providing written feedback to

explain that the issue was reviewed. Staff explained the investigative team's process and clarified that, when they contact reporters by phone, it is typically to educate the member and explain that the event that was reported is permitted by policies and bylaws, so it will not be reviewed. The member also suggested an executive summary to HRSA instead of monthly reports, and staff explained that the monthly report was a direct HRSA request.

A committee member stated that the format and detail was great and favored a monthly cadence, but requested additional information about a specific case. Staff agreed to research the details of that case and provide them in the following day's closed session. Staff also explained that one of the things for the committee to consider is potential for referrals based on patterns or trends seen in the cases and provided the example of multiple requests for certain test types that current policy does not require be performed. Another committee member suggested obtaining additional data on organs allocated but not transplanted. A committee member suggested that staff are likely receiving the minority of surgical damage cases because in their experience, OPOs have a robust system of tracking surgical damage and communicating back to the recovery surgeon's facility.

A committee member asked about the cadence of reviewing the report, expressing concern that the MPSC may review the reports at a slower cadence than HRSA. Staff explained the process for HRSA to receive the first report and provide any feedback and that the very nature of the MPSC reviewing the data helps HRSA achieve the goal of experts reviewing the data instead of just staff. Staff explained that one change under consideration is the timing of providing the outcome of the case to the member, as they want to ensure staff don't prematurely close a case that, after receiving this report, the MPSC identifies a potential issue that needs additional discussion.

In conclusion, the MPSC will regularly receive information including but not limited to:

- The number of reports submitted
- The method of receipt, such as the Improving Patient Safety Portal, Member Reporting Line, and referrals from Patient Services
- Whether the reporter was an organ procurement organization, transplant program, histocompatibility laboratory, patient or donor family member, anonymous reporter, etc.
- Whether the report was a self-report or about another organization
- The number of reports that are still pending review, referred to the MPSC for action according to the OPTN Bylaws, Appendix L, or are not forwarded for an MPSC action
- For cases not referred to the MPSC for formal action, the MPSC will receive a brief summary of the nature of the reports and investigative findings that led to staff's determination not to forward for MPSC review

Staff will revise its processes and documentation so that cases are not formally closed until the MPSC has received the information described above about a case. The committee will review additional reports at its December 2022, January 2023 and February 2023 meetings. The Committee will continue to refine this process, including making necessary changes to the content and frequency of the report, as it evaluates additional data.

4. Wakefield Criteria and Required Member Reports to the OPTN

The current OPTN contract requires staff to report to HRSA all required patient safety events identified in a 2011 letter from former HRSA Administrator, Mary K. Wakefield, PhD, R.N. to the OPTN President at the time, John Lake, M.D., in the timeframes specified within the letter. These requirements are referred to as the "Wakefield criteria." HRSA previously asked staff to also include MPSC leadership when notifying HRSA of Wakefield criteria events. The MPSC discussed whether the full Committee should also

receive updates on Wakefield criteria reports, or whether the MPSC wished to be informed of alternative types of reports quickly, or perhaps even immediately, to ensure that potential issues are escalated in a timely fashion and to increase the involvement of the MPSC in investigative activities. The MPSC reviewed the Wakefield criteria that staff use to identify which types of reports require notification to Committee leadership and HRSA ex-officio members, and the timeline for escalation, and determined that the current process works as intended. Specifically, the MPSC noted notifying and obtaining feedback from MPSC and HRSA representatives while an investigation is ongoing has proved to be an effective approach. The MPSC did not feel staff needed to escalate reports to the full Committee prior to the conclusion of the investigation.

Though the MPSC determined the process for escalating reports works well, the MPSC did note that the types of cases staff are required to escalate does not align with member obligations to report specific events for MPSC review. OPTN Polices specify reporting of certain, specific events. For example, Policies 15 and 18 require members to report potential donor-derived disease transmissions, certain living donor adverse events, and patient and graft failures. Additionally, the OPTN Bylaws, Article 1.1.G require members to report instances of potential noncompliance with OPTN obligations. However, though staff are required to report the near miss of a transplant into the wrong recipient or the transplant of the wrong organ into a recipient per the Wakefield criteria, members are not explicitly required to report these events to the OPTN. Between December 1, 2021 and October 31, 2022, staff received 497 total reports to the OPTN. However, to help ensure the MPSC is aware of certain safety situations in a timely manner, the MPSC intends to sponsor a project to clarify specific types of events members are required to report to the OPTN. The project will also include whether to require reporting of other kinds of safety events, even if not required by the current Wakefield criteria.

5. Monitoring Descriptions and Plans for New Policies

Staff presented an overview of current member compliance monitoring processes and resources including potential changes for the Committee to consider in the future for new policy and bylaw changes. The presentation included the current effort to enhance member compliance monitoring, which includes evaluating all aspects of current monitoring, opportunity for strengthening involvement in the policy and bylaw development process, identifying new ways to monitor member compliance, and assessing the MPSC's role throughout the process.

The presentation highlighted what influences the ability to comprehensively monitor policy and bylaw as well as misconceptions about current member compliance monitoring.

Following the presentation the Committee discussed perceptions about MPSC oversight, particularly erroneous assumptions that the MPSC has compliance data available for every OPTN member on every OPTN policy. To ensure the MPSC has compliance data available when needed, the MPSC agreed the Committee should be more engaged in discussing new OPTN policy requirements and how the MPSC will monitor member compliance with those policies. Specifically, the MPSC hopes increased communication during the policy development process can help ensure that either programming or data collection will be available for the MPSC to effectively and systematically monitor compliance with the policy, or to ensure that all stakeholders are aware of potential limitations on our ability to systematically evaluate compliance. The MPSC also discussed the need to consider what compliance data can be collected and shared as a part of the sponsoring committee's evaluation of the policy effectiveness. The MPSC supported ideas to tailor monitoring for new policy requirements. For example, the MPSC could more closely monitor member compliance immediately after implementation and relax monitoring activities once most members demonstrate compliance with the new policy.

Summary of discussion:

- The Chair noted that while they served on the OPTN Policy Oversight Committee part of the discussion was whether or not a new project could be measured so it could be monitored and felt that was an avenue for the MPSC to be a part of that process. The Chair also mentioned there have been projects where the benefit to candidates outweighed waiting for data collection to allow for more comprehensive monitoring at implementation. Staff added that the part of the process is going to be weighing the pros and cons of being able to comprehensively monitor projects versus the community need for implementation and that while monitoring is discussed during the policy making process, it is often in reference to research monitoring and not member compliance monitoring. A member expressed that if the OPTN is going to take the time to develop new policies or bylaws that they should be followed-up on and offered that one way to do that could be to ask members for feedback on any difficulties or benefits associated with the implementation.
- Another member asked if the MPSC would be monitoring the newly implemented *Establish Minimum Kidney Donor Criteria to Require Biopsy* in real-time or if it would be evaluated retrospectively. Staff explained the policy does not require a biopsy to be performed, but rather requires OPOs to document the reason why a biopsy was not performed in certain situations. However, the OPTN is not proactively collecting the reasons why biopsies were not performed and therefore compliance cannot be monitored in real time. The OPTN also does not collect data for each of the minimum kidney donor criteria, and therefore staff are unable to identify each instance in which an OPO must make reasonable efforts to complete a biopsy. Any monitoring for this policy will require reaching out to the OPOs to gather information.
- A member felt that trying to monitor all existing policies would be a heavy lift but added that it does make sense for new policies. They noted that the MPSC should take direction from staff regarding what policies need closer monitoring.
- Staff asked for additional feedback on any impacts for explicitly documenting when a change cannot be comprehensively monitored, if there would be any challenges with increasing the immediate post-implementation member compliance monitoring, and if there are appropriate timeframes for members to come into compliance with any changes.
- A member shared that their program has to make similar decisions when releasing new policies or procedures to assess why they are making the change and what is the risk exposures are. The degree and timeliness of change monitoring is determined by that discussion. If there is a high risk for patient safety, they will do a full audit soon after the implementation, but if it is not critical the roll-out can happen more slowly. The member asked that if there is an opportunity for short-term data collection outside of OMB approval to allow for member compliance monitoring and staff explained that any new data collection would be subject to OMB approval which is limiting.

6. Membership Bylaws Proposed Corrections

Staff presented two non-substantive corrections to the OPTN bylaws for the Committee's consideration and vote.

Donor ID Definition

The first proposed correction was the removal of the "Donor ID" definition from Appendix M, Definitions to correct an inadvertent substantive change that was made during the OPTN Bylaws plain language rewrite. Appendix M, Definitions was a new addition to the OPTN Bylaws. The definition of "Donor ID" in Appendix M limited it to the OPTN generated ID. The purpose of the plain language rewrite effort was to

produce bylaws that were easier to understand, access, and use without making substantive changes to the bylaws. The inclusion of the "Donor ID" definition combined with a change to the procurement and procurement observation log requirements to include a "Donor ID" rather than a "medical record and/or UNOS identification number" unintentionally changed the transplant program key personnel requirements to exclude the use of foreign experience to meet procurement and procurement observation experience requirements. This substantively altered requirements, which was not the intention of the rewrite, and created an unintended barrier to qualified personnel seeking designation as primary surgeon or physician. Removal of the definition allows for a broader interpretation of Donor ID in the OPTN Bylaws that would be inclusive of foreign experience, correcting the unintentional change.

The Committee requested clarification on whether the term Donor ID would be removed throughout the bylaws, and if so what it would be replaced with. Staff clarified that only the definition in Appendix M would be removed allowing for the intended broad interpretation of the term Donor ID elsewhere in the OPTN bylaws.

The Committee approved the following resolution:

> **RESOLVED**, that the Membership and Professional Standards Committee recommends approval of removal of the Donor ID definition from OPTN Bylaws, Appendix M to the Board of Directors.
>
> The motion was approved with 30 For, 0 Against, and 0 Abstentions.

Histocompatibility Laboratory Director Certifications

The second proposed correction was to update bylaw language in Appendix C.3.A (*Histocompatibility Laboratory Director Qualifications*) to reflect changes to histocompatibility laboratory director certification naming conventions made by a non-OPTN certifying body. Appendix C.3.A, Pathway 2, Requirement 3 of the OPTN bylaws includes the American Board of Histocompatibility and Immunogenetics Diplomate (ABHI(D)) as a qualifying certification option. This certification was issued upon the passage of the Diplomate exam. ABHI's name changed to the American College of Histocompatibility and Immunogenetics (ACHI), and there are two new ACHI certifications that require passage of the Diplomate exam, the ACHI Associate (ACHI(S)) and the ACHI Fellow (ACHI(F)).

The Committee considered two options for correcting the bylaw language to be inclusive of both the new certification naming conventions and historic certification:

Option 1: The proposed clarification would add reference to the Associate and Fellow certifications to Appendix C.3.A, Pathway 2, Requirement 3, to reflect a change to the name of the certifying Board and new certifications that are equivalent.

Option 2: The proposed clarification would remove reference to Certification as a Diplomate by ABHI from Appendix C.3.A, Pathway 2, Requirement 3, and replace it with reference to any ABHI or ACHI certification that requires passage of the ABHI or ACHI Diplomate exam.

In the discussion that followed, a committee member expressed preference for Option 1, as it clearly denotes the certification options that will meet bylaw requirements and would be less likely to cause confusion for OPTN members. Another committee member noted that the paragraph format was confusing, as it was not clear whether an individual must have one or all of the listed certifications. The Committee requested that all certification options be put into a bulleted list format, to make it clear that only one of the certification options is necessary to meet the requirement. Staff reformatted Option 1 as requested, and the Committee voted to proceed with the amended Option 1:

3. One of the following ~~C~~certification<u>s:</u> ~~as a~~

- Diplomate by the American Board of Histocompatibility and Immunogenetics~~,~~
- Associate by the American College of Histocompatibility and Immunogenetics
- Fellow by the American College of Histocompatibility and Immunogenetics
- High complexity laboratory director by the American Board of Bioanalysis~~,~~
- Diplomate by the American Board of Medical Laboratory Immunology

The Committee approved the following resolution:

> **RESOLVED**, that the Membership and Professional Standards Committee recommends approval of Option 1 correction, as amended, to histocompatibility laboratory director qualification certifications to the Board of Directors.
>
> The motion was approved with 32 For, 0 Against, and 0 Abstentions.

Both proposals will be presented for consideration during the December 5, 2022, Board of Directors meeting.

7. Performance Monitoring Enhancement (PME) Project Update

Staff provided an update on the MPSC Performance Monitoring Enhancement Project. This new monitoring system involves four risk-adjusted measures related to the patient journey: 90-day graft survival hazard ratio, 1-year conditional on 90-day graft survival hazard ratio, the offer acceptance rate ratio, and the pre-transplant mortality rate ratio. The project has a phased implementation. In July 2022, the MPSC implemented the two post-transplant graft survival metrics. The MPSC will implement the organ offer acceptance rate ratio in July 2023, and the pre-transplant mortality rate ratio in July 2024

Staff presented initial limited post-implementation monitoring data and a list of all the metrics that will eventually be included in the post-implementation monitoring updates. This presentation focused on organ-specific rates of new waitlist additions from January 1, 2020 through September 30, 2022, for kidney, liver, heart and heart-lung, lung, and pancreas and kidney-pancreas.

Review of the data does not illustrate any changes from the normal fluctuations in the number of daily registrations since the approval of the performance monitoring enhancement proposal in December of 2021.

The Committee will need to decide what will be considered the intervention date for future post-monitoring data reports since the implementation for this proposal is phased with different metrics being implemented at different times. The intervention date could be the date of approval, date of first information being provided to members on their standing in relation to the new MPSC criteria, or the actual implementation date of each metric for those measures intended to evaluate the effect of use of that metric. The intervention date would be determined based on when the MPSC expects behavior may change based on these new metrics.

The Committee was given an opportunity to ask questions or provide comments. The Subcommittee Chair reinforced that it is very early to evaluate any effect of the new metrics on waiting list registrations. He noted he is looking forward to future reports once the metrics had been implemented. It is very important that the Committee review the effects of these metrics on the vulnerable populations described in the full post-implementation monitoring plan in addition to the general population.

Offer Acceptance Collaborative

Staff provided an update on the planned offer acceptance collaborative, which will support the MPSC's implementation of the offer acceptance rate ratio metric in July 2023. The collaborative is being developed to share effective offer acceptance practices and help transplant programs utilize improvement activities to increase their offer acceptance rates. Staff shared a summary of the aim and purpose of the collaborative and of the collaborative improvement model. Staff then gave an overview of the timeline for the offer acceptance collaborative with particular emphasis on the efforts staff are focusing on currently, which include conducting key informant interviews to support work on resources for the OPTN toolkit and the Improvement Guide for the collaborative, and developing an interest form and project guidelines and sending the interest form to members. Staff sent an email to primary transplant program administrators on October 24, soliciting interest in participating in the collaborative. Staff described the plans for the offer acceptance collaborative kick-off conference that will be held over one and a half days on January 31 and February 1. The conference will be a hybrid, incorporating a virtual plenary component open to all members and in-person focused sessions for collaborative participants. The floor was opened to questions and discussion.

- The Chair asked, since this is open to all organ programs, how will staff deal with a large response from members and how decisions will be made as to who participates. Staff welcomed feedback on this topic and are having internal discussions on how to make these decisions. Based on past experience with new collaboratives the criteria are not establish for how to choose participants until staff gets a sense of the level of interest.
- A couple of transplant program administrators asked when the email was distributed and how it was addressed. Once the process was described, committee members suggested that a follow-up email be sent from an individual rather than from UNOS Communications and the topic line reference the collaborative. Another member suggested sending the communication to the primary physicians and surgeons as well. A member also suggested highlighting in the email that the conference and collaborative will include transplant programs that have higher than expected offer acceptance rate ratios sharing their experience. Staff noted we will also be doing some general marketing efforts to encourage participation in the conference, in addition to the collaborative.
- A member asked if staff could provide the slide deck to individuals so they could share it with their programs to illustrate the concept and purpose of the collaborative.
- With regard to the kick-off conference, a member suggested that an SRTR representative present a deep dive on the impact of using perceived higher risk donors on the observed to expected ratio for offer acceptance and post-transplant outcomes. This may encourage programs to be more willing to improve their utilization of these organs based on an understanding that it can help their observed to expected ratios rather than hurt them. A member noted that this effort could provide a great opportunity to promote the use of kidney offer filters and examine the role of provisional yes in the allocation process to support other initiatives within the OPTN.
- A member asked whether OPOs will be involved in the conference and collaborative to provide information on OPO challenges and practices. Staff noted that we can build this topic into the conference.

Staff provided information on the next steps, which include continued updates on the offer acceptance collaborative and conference, and beginning work on the development of the review tools and process for programs that are identified by the offer acceptance criteria.

8. Educational Initiatives

Staff updated the Committee on the status of various MPSC educational initiatives. Staff explained that MPSC members review and discuss each ongoing initiative, and provide ideas for future educational initiatives. Staff also explained the new process for reporting all potential policy issues and policy-related referrals to the Policy Oversight Committee (POC). Staff shared ongoing educational efforts and ideas that were presented at the Transplant Quality Institute this year as well as information on upcoming abstract deadlines and conferences.

Policy-Related Referrals

Under the current process, the MPSC reviews instances of non-compliance and refers issues to specific OPTN Committees for evaluation. The Committee that receives the referral then decides whether to pursue the issue or not. Staff explained that action is not always taken on referrals sent by the MPSC.

Going forward, the MPSC will review instances of non-compliance and identify a need for policy revision or data collection. A project form will be created as a project idea with MPSC as the source of the idea and submitted to the Policy Oversight Committee (POC). Then, the POC will prioritize work on the MPSC suggestions. The POC and MPSC will report on referral activities to the OPTN Board of Directors (BOD). The new proposed process would also look to incorporate compliance findings into post-implementation reports when possible. Staff explained that the new process intends to:

- Increase transparency by sharing MPSC recommendations during system level discussions at the POC and BOD.
- Allow the POC to incorporate MPSC recommendations into the project portfolio as appropriate.
- Improve the system by increasing the number of MPSC referrals that are acted upon.

Staff shared examples using current MPSC referrals. With the MPSC's approval, some of these referrals would be included in the next report to the POC. The examples included a description of the problem, the relevant policies or bylaws and MPSC suggestions, evaluation of whether the issue fits within an OPTN Strategic Plan Goal or POC Strategic Policy Priority, patient impact, and any available, applicable data.

The MPSC reviewed a list of referrals and supported including the following in a project report to the POC:

- Develop a centralized system to track deceased donor vessel availability
- Consider revisions to Policy 16.6.B (*Extra Vessels Storage*) such as allowing storage of HCV positive vessels and storage for more than 14 days.
- Evaluate potential policy revisions to clearly outline permissible and prohibited behavior by individuals that may be employed at a donor hospital and by the OPO.

Ongoing and New Referrals

Staff provided an update on the status of recent referrals, which included:

- Use of liver and heart pediatric emergency exception pathways: Data regarding use of the emergency exception pathway and review of instances where the candidates did not meet the criteria were presented to the Pediatric Transplantation Committee. Based on the data presented, the Pediatric Transplantation Committee is planning to form a workgroup to examine the issue.

- Streamline donor assessment and evaluation procedures and communications of updated donor and recipient information: Aligns with existing Operations and Safety Committee project for automated donor test result reporting in UNet[sm] and work is slated to start on the project in April 2023.
- Consider whether HOPE Act requirements apply to any donor with at least one positive HIV test result, or a clinical determination based on all available tests. An MPSC member shared an update with the committee. She reported that the Centers of Disease Control (CDC) is working with OPTN Disease Transmission Advisory Committee (DTAC) on testing guidance. She also reported that on November 17, the Advisory Committee is meeting to discuss recommendations for removing HOPE ACT research criteria for liver and kidney donors.

The Committee recommended new educational initiative ideas, which include:

- Streamlining a process for reporting patient safety events (notification, patient safety follow-up, receiving and disseminating information). MPSC members stated that there should be one consistent policy, especially with greater organ sharing and working with OPOs outside of locality.
- Guidance document to OPOs about expedited kidney placement.
- A tool or form to assist programs with review of mortalities. An MPSC member stated that this tool could be helpful for programs to understand how to analyze adverse events in an effective way.
- An educational resource to assist programs with understanding how to put together a Corrective Action Plan (CAP).
- Webinar or presentation on shared learnings from CAPs for training new transplant coordinators and/or OR staff

Living Donor Event Project Update

Staff presented an update on the MPSC Living Donor Event project, which aims to share information with the transplant community on the incidence of living donor events and the lessons learned from MPSC reviews to promote effective practices.

The work group, composed of previous and current MPSC members, initially focused on living kidney donor deaths within 2 years of donation. The work group reviewed in more depth the categories of living donor deaths that have a potential to be related to donation including complications during recovery procedure, medical issues, suicide or potential suicide and overdose. Currently, staff are combining summaries drafted by work group members into a draft article to be reviewed and edited by the work group. In addition, this topic has been submitted a potential presentation at the next Transplant Management Forum.

Patient Safety Project Update

Staff presented an update on the MPSC Patient Safety Project, which aims to share information with the transplant community to heighten awareness of safety, promote effective practices and prevent future occurrences.

The Patient Safety Workgroup met on August 12, 2022 and discussed which educational topics to prioritize and potential methods of sharing information. The group felt that focusing on critical transplant processes was appropriate as opposed to one specific category, so the group can develop guidance on multiple important processes. The workgroup felt that creating de-identified case studies,

based on real events reported to the OPTN, would be the most instructive in educating the community. Additionally, the workgroup felt that interactive modules or PowerPoint presentations with a voiceover, illustrating serious patient safety situations and how to navigate them would also be instructive. They also discussed the possibility of creating a MPSC insights playlist in UNOSConnect to store the resources created.

Staff presented at the Transplant Quality Institute conference in October and introduced the Patient Safety Project. Staff presented high level case information involving serious safety events reported to the OPTN, and shared some common themes, process inefficiencies and effective practices, based on the MPSC's review of these events. The information presented was well received by attendees and they appreciated the case information and effective practices shared.

The next workgroup meeting is on December 2, and the group will discuss a number of serious safety events identified for project review. After case review, the group will begin drafting resource content and staff will work with various teams to develop a plan for distribution. Once this is complete, a final draft will be reviewed by the MPSC before sharing with the community.

Upcoming Meetings

- December 8, 2022, 1-3pm, ET (Virtual)
- January 20, 2023, 3-5pm (Virtual)
- February 16-17, 2023, Chicago, IL
- March 20, 2023, 3-5pm (Virtual)
- April 24, 2023, 3-5pm (Virtual)
- May 22, 2023, 3-5pm (Virtual)
- June 21, 2023, 3-5pm (Virtual)

Attendance

- **Committee Members**
  - Maher Baz
  - Alan Betensley
  - Emily Blumberg
  - Timothy Bunchman
  - Anil Chandraker
  - Todd Dardas
  - Robert Fontana
  - Reginald Gohh
  - Barbara Gordon
  - Lafaine Grant
  - Robert Harland
  - Kyle Herber
  - Victoria Hunter
  - Ian Jamieson
  - Christopher Jones
  - Andrew Kao
  - Peter Kennealey

- Catherine Kling
- Michael Kwan
- Dianne LaPointe Rudow
- Scott Lindberg
- Melinda Locklear
- Gabriel Maine
- Amit Mathur
- Kenneth McCurry
- Nancy Metzler
- Dan Meyer
- Regina Palke
- Michael Pham
- Elizabeth Rand
- Sara Rasmussen
- Pooja Singh
- Jason Smith
- Zoe Stewart Lewis
- Laura Stillion
- J. David Vega
- Candy Wells

- **HRSA Representatives**
  - Jim Bowman
  - Shannon Dunne
  - Arjun Naik
- **SRTR Staff**
  - Ryutaro Hirose
  - Jonathan Miller
  - Bryn Thompson
- **UNOS Staff**
  - Sally Aungier
  - Matt Belton
  - Tameka Bland
  - Tory Boffo
  - Kate Breitbeil
  - Rebecca Brookman
  - Shawn Brown
  - Tyrone Brown
  - Aileen Corrigan-Nunez
  - Tommie Dawson
  - Robyn DiSalvo
  - Nadine Drumn
  - Demi Emmanouil
  - Katie Favaro
  - Liz Friddell
  - Michelle Furjes
  - Jasmine Gaines
  - Shavon Goodwyn

- Asia Harden
- Morgan Jupe
- Margaret Kearns
- Kay Lagana
- Krissy Laurie
- Trung Le
- Ann-Marie Leary
- Ellen Litkenhaus
- Jason Livingston
- Maureen McBride
- Anne McPherson
- Sandy Miller
- Amy Minkler
- Steven Moore
- Rene Morgan
- Sara Moriarty
- Leonce Moses
- Rebecca Murdock
- Heather Neil
- Alan Nicholas
- Yaway Nicholson
- Samantha Noreen
- Jacqui O'Keefe
- Beth Overacre
- Rob Patterson
- Michelle Rabold
- Liz Robbins Callahan
- Sharon Shepherd
- DeeDee Simmons
- Dale Smith
- Susie Sprinson
- Olivia Taylor
- Stephon Thelwell
- Melissa Tisdale
- Anna Wall
- Marta Waris
- Betsy Warnick
- Trevi Wilson
- Claudia Woisard
- Emily Womble
- Karen Wooten
- Carson Yost
- Amanda Young

- **Other Attendees**
  - Martha Camden