OPTN Membership and Professional Standards Committee
Meeting Summary
March 5-7, 2024
Detroit, MI

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Introduction

The Membership and Professional Standards Committee (MPSC) met in person with a virtual option in both open and closed session on March 5-7, 2024, to discuss the following agenda items:

1. Public Comment Proposals
2. Expeditious Task Force Update
3. Report of Investigative Activities
4. OPO Performance/HRSA Directive Update
5. Executive Committee OPTN Strategic Plan 2024-2027
6. Membership Requirements Revision
7. Performance Monitoring Enhancement Update
8. Report of Investigative Activities
9. Compliance Issues
10. Performance Issues
11. Offer Acceptance Review
12. Estimated Glomerular Filtration Rate (eGFR) Update
13. Membership Issues
14. MPSC Education/Communication Initiatives and Policy Referrals

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

1. Public Comment Proposals

- Standardize the Patient Safety Contact and Reduce Duplicate Reporting

The Vice Chair of the ad hoc Disease Transmission Advisory Committee (DTAC) presented the Committee's proposal Standardize the Patient Safety Contact and Duplicate Reporting, which is currently out for public comment. This project originated as a referral from the MPSC to the DTAC.

Meeting Summary:

A member inquired about the potential to use this notification process through a mobile device, highlighting the necessity for mobile accessibility to meet the 24-hour response time. A member asked about the transplant hospital's responsibility for responding to various types of culture reports, specifically if there would be different acknowledgment requirements for required reportable transmissions versus negative cultures. The presenter answered that all post-procurement test results will require an acknowledgment of receipt by the patient safety contact (PSC).

A member inquired if the initial test result notification would go to both the primary and secondary PSC, or only go to the secondary PSC if the primary did not respond in a certain period of time. The presenter responded that the initial notification would go to both the primary and the secondary contact with the

intent that someone at the transplant hospital is aware of the post-procurement test results. A member questioned if a group distribution email could be used as a PSC in place of a specific individual, to which the presenter answered yes, group emails are acceptable PSCs. A member voiced support for requiring the PSC to work at the member organization, emphasizing that this is an important requirement while the OPTN is unable to provide oversight to contractors.

A member expressed support for this proposal to improve the disease reporting and communication process. In response to the question of potential concern for patient safety reasons, a member provided the OPO perspective that there is extensive documentation and reporting associated with disease transmission. The member highlighted the extensive reporting required for eye and tissue donors to maintain FDA regulation and that those processes are often applicable for all organ types.

A member noted that this policy requires action on organ procurement organizations (OPOs) and transplant hospitals, but not histocompatibility laboratories. The member inquired if there are different protocols when labs are storing cultures that are positive for HIV or Hepatitis C. A member from a histocompatibility lab clarified that there is no difference in the protocol for storing cultures based on infectious disease potential. A member questioned if OPOs would still be required to notify the OPTN of the test results that they receive from a transplant hospital, to which the presenter clarified that this proposal would reduce the duplicate reporting requirement for OPOs that currently exists.

- Inform only proposals

OPTN Contractor staff presented a general overview of three public comment items, *Clarify Requirements for Pronouncement of Death* sponsored by the Organ Procurement Organization (OPO) Committee, *Refit Kidney Donor Profile Index without Race and Hepatitis C Virus* sponsored by the Minority Affairs Committee (MAC), and *Proposal to Address the Relationship of the OPTN and OPTN Contractor Boards* sponsored by the Executive Committee. The OPO Committee proposal originated as an MPSC referral to clarify any potential conflict of interest between individuals who declare death and participate in organ recovery. This proposal does not have monitoring implications. The MAC proposal removes black race and positive Hepatitis C and rebalances the Kidney Donor Profile Index (KDPI), which would be done through a system change and does not require action on behalf of members or have monitoring implications. The Executive Committee proposal is out for a special public comment cycle and removes the requirement from OPTN Bylaw 2.8 for the OPTN Board of Directors to be identical to the OPTN Contractor's Board of Directors and prohibits members from serving on both Boards except for the OPTN Executive Director. MPSC members are encouraged to review these three proposals and provide their own public comment.

2. Expeditious Task Force Update

The Committee and Expeditious Task Force (ETF) engaged in a comprehensive discussion aimed at enhancing deceased donor transplants and operational efficiency within the transplantation ecosystem. Recognizing the need for strategic alignment, they opted to prioritize deceased donor transplants while deferring considerations of living donor transplants for the time being. This strategic decision was informed by the desire to emulate the success of top-performing programs, drawing inspiration from transformative changes within the healthcare landscape.

In delineating the Task Force's initiatives, the Committee scrutinized OPTN policies perceived as impediments to efficiency and utilization. Notably, they deliberated over potential policy changes, including the proposal for a moratorium on post-transplant outcome monitoring and the abolition of consent for high Kidney Donor Profile Index (KDPI) kidneys. The ensuing discussion underscored the need for clear patient communication, leading to considerations of alternative indicators to facilitate informed decision-making.

In addressing barriers to growth and financial feasibility, particularly in engaging transplant hospitals and payors, the committee explored various strategies. These encompassed targeted outreach initiatives aimed at hospital c-suite executives, as well as endeavors to align metrics with regulatory bodies such as CMS and HRSA.

Initiatives aimed at investigating non-use/non-utilization of organs and designing rescue pathways to optimize organ utilization were met with thorough deliberation. Feedback received on proposed initiatives emphasized the principles of equity, transparency, and member compliance.

The committee further discussed the challenge of prioritizing initiatives within the constraints of limited bandwidth. While emphasizing the significance of the bold aim, they underscored the importance of developing strategies to effectively engage stakeholders.

In conclusion, the committee reiterated the imperative of collaborative efforts, stakeholder engagement, and evidence-based decision-making to realize their objectives in enhancing deceased donor transplants and operational efficiency within the transplantation domain.

3. Report of Investigative Activities

Staff presented aggregate data on reports made to the Patient Safety team between October 2023-January 2024. Staff explained that instead of presenting just the prior month's data, in the spirit of continuous process improvement, staff altered the in-person MPSC meeting presentation to instead provide cumulative data since the last time in-person meeting. Staff will continue to provide monthly Reports of Investigative Activity as part of the monthly conference call meeting materials.

Staff shared cumulative data on the types of reports received by month and as a percentage of the total. Staff also provided data on reporter types and comparison of reports that were self-reported and those wherein the reporter was filing a complaint against another member. Finally, staff shared common themes in cases that staff closed without forwarding to the MPSC for review. Those themes were a referral to another team that performs routine monitoring of that issue, deviations in practice from what members are used to that are not out of compliance with OPTN obligations, and reports made by non-members that are not under the purview of the OPTN and are not patient safety issues. There were no comments or questions from the committee.

4. OPO Performance/Health Resources and Services Administration (HRSA) Directive Update

OPTN staff gave an update on the status of the OPO Performance Monitoring Enhancement (PME) project and how work has shifted to focus on the HRSA Data Directive.

The original plan for the project was split into two phases, the first phase focusing on development of a concept paper on consistent and improved data collection, and an Electronic Donor Record (EDR) tool to collect data and then a data collection proposal to transfer the information to the OPTN computer system. The concept paper was approved for Winter 2024 public comment before being placed on hold. The second phase includes the development of performance metrics for use in OPO quality improvement and in the Committee's evaluation of OPO performance once sufficient data is collected.

The OPO PME workgroup redirected their efforts to work on feedback to be provided to HRSA to inform a future Health and Human Services Secretarial Directive on a draft ventilated referral notification data collection. From November 2023 to January 2024, expedited review was conducted by the OPO PME workgroup to prepare feedback, which was submitted on January 31, 2024.

Staff gave an overview of themes of the OPO PME workgroup's feedback, which included recognition of the common goal of HRSA, CMS, the MPSC workgroup, and OPOs to collect data on all phases of

donation, concern that the data collected in the HRSA draft form was not granular enough to ensure collection of meaningful and useful data, and may not meet the intent to determine donor potential and reasons referrals do not proceed to donation.

Staff reviewed the high-level feedback that the OPO PME workgroup provided on the data fields included in the draft form, indicating that feedback focused on 36 new data fields and whether collection is feasible with or without clarification, would pose significant burden, or are outside of the scope of the OPTN. Feedback included potential advantages, challenges, and pitfalls to collection of specific data fields. The OPO PME Workgroup Chair highlighted the need for standardized definitions of fields to ensure completeness and consistency of the data, noting lack of definitions in the drafts provided by HRSA. He encouraged providing feedback during the Federal Register public comment period for the 2023 OPTN Data Systems Office of Management and Budget (OMB) package.

Staff stated that the Secretarial Directive was issued on February 5, 2024. Staff explained the role of the OMB as the authority providing clearance for government data activities, including OPTN data collection. The process includes HRSA posting notices in the Federal Register (FRNs) for both a 60- and 30-day public comment period. While the Data Advisory Committee (DAC) and OPO PME workgroup feedback was not included in the directive, it will be incorporated in the forms as part of the 60- and 30-day notices of the OMB process. A collective OPTN response will be drafted in response to the 60-day FRN, which will include, at a minimum, DAC, MPSC, OPO Committee, Transplant Administrators Committee, and OPO PME Workgroup input. Since the public comment process will differ from the usual OPTN process, additional communication will be provided to the community to ensure adequate opportunity to provide feedback.

The concept paper that was placed on hold will be revisited by the Executive Committee after the 60-day FRN comment period.

Summary of Discussion:

A member asked whether an Application Programming Interface (API) for transfer of forms is still being discussed. Staff responded affirmatively, noting that this will likely be included in the OPTN response to the 60-day FRN to ensure data collection in the most meaningful and least burdensome way. The OPO PME Workgroup Chair encouraged scheduling of ample time for the workgroup to provide detailed, robust feedback for the public comment that will help ensure quality data collection.

5. Executive Committee OPTN Strategic Plan 2024-2027

The Vice President of the OPTN presented the 2024-2027 Strategic Plan proposal on behalf of the OPTN Executive Committee. If approved by the OPTN Board of Directors, the new strategic plan will go into effect on July 1, 2024.

Meeting Summary:

A member voiced support for the strategic plan but noted that a lot of variety exists between transplant hospitals nationwide and a ‘one size fits all’ approach may not be the best method for developing metrics. The presenter agreed with the variability in transplant programs based on factors such as population or geography, but the purpose of the strategic plan is to be a national plan to guide the OPTN as a system. A member inquired if the Executive Committee considered any system efficiencies in the donation process, noting the expansion of donor processing time from consent to cross-clamp over the past two decades. The member recommended considering factors beyond distance in the efficiency component of continuous distribution, to which the presenter agreed and responded that the OPTN President has charged the organ-specific committees with evaluating how efficiency can be better integrated into the new allocation framework. A member also recommended modifying the metric of

measuring non-use rate by donor service area (DSA) since DSA's are a geographic distinction reflective of OPOs and OPOs are not the ones that use organs.

6. Membership Requirements Revision

OPTN Staff reviewed components of the Membership Requirements Revision Proposal for Appendices A, B, and D to familiarize the Committee with the content and address issues that may result in updates to the proposal, and to prepare members for breakout discussions of the changes and key issues.

The project is split into three phases, with Phase 1.A focusing on the current proposal and developing a framework for key personnel training and experience requirements. Phase 1.B will look at Appendix K: Inactive Waiting List, Program Inactivation, Withdrawal and Termination, and Appendix C: Histocompatibility Lab Requirements. Phase 2 includes applying the framework for key personnel to the organ-specific Appendices E – J by working with organ-specific committees, and potentially developing requirements for third party membership. Staff provided an overview of the considerations for revisions developed by the MPSC, including compliance with the Final Rule, support for periodic reassessment of membership status, consistency with current practice and qualifications, reduced complexity to simplify the application process and review, and ways to stratify requirements based on the type of application.

Staff also informed the Committee of small changes that will be made to clean up the proposal prior to Committee consideration of whether to release the proposal for Summer 2024 public comment. A review and discussion of the bylaw appendices included in the proposal followed.

Appendix A, *Membership Application and Review*: Summary of Changes and Discussion

Staff gave an overview of the purpose of and planned changes to Appendix A, including small changes to other bylaw areas to reflect the Appendix A changes. The changes include the elimination of interim approval, delegation of authority to approve applications from the Board of Directors to the MPSC, consolidation of the tracks available after an application is rejected, and language changes for clarity within the re-application section.

During discussion, Staff asked for the Committee's feedback on the language in the re-application section, and modified the language based on suggestions received.

Summary of Discussion:

Members suggested the addition of an avenue for individuals previously approved in key personnel roles to go through an abbreviated application process when the Committee begins looking at the organ-specific appendices for key personnel. A member also highlighted the need to address third-party companies contracted by OPTN members as part of this project. A member asked if the bylaws needed to address communication with the board in the bylaws as part of the proposed change in authority to approve applications passing from the Board to the Committee. Staff responded that a practice can be put in place without codifying it in the bylaws. Information on the approval of applications could be included in the Committee's twice-yearly report to the Board, like what is done for other case types.

Appendix B, Membership Requirements for Organ Procurement Organizations (OPOs): Summary of Changes and Discussion

Staff gave an overview of the purpose of and planned changes to Appendix B. The changes include reorganization to clearly delineate initial membership criteria from requirements for members to align

with the Final Rule, and elimination of redundant requirements and requirements outside the purview of the OPTN.

A member asked how OPO mergers will be handled due to the new CMS requirements. Staff clarified that recent OPO mergers can be used for reference, and that each merger is typically assessed to determine what application materials are necessary.

Summary of Discussion:

The Committee discussed the addition of the Primary Data Coordinator personnel role to OPO requirements, with comments indicating lack of support for the addition of this requirement, citing the ability of the OPTN to require this without it being included in the bylaws, and potential burden of a more complicated OPTN staff change process created by adding it to the bylaws. The Committee also discussed whether the language in Appendix B.2.F: *Other OPO Personnel* should be broader to include aspects of OPO responsibility other than organ recovery and distribution. Committee feedback discouraged duplication of CMS regulations in the bylaws.

A member asked about organ yield metrics, and whether changes to OPO metrics will happen as part of this proposal. Staff clarified there is no change to the metrics as part of this proposal, but noted there is a separate Committee project on OPO performance monitoring.

A member asked whether a reference to the recent new requirements for site security administrators and information security contact needs to be included. Staff clarified that the Network Operations Oversight Committee has oversight over that requirement.

Appendix D, Membership Requirements for Transplant Hospitals and Transplant Programs: Summary of Changes and Discussion

Staff gave an overview of the purpose of and planned changes to Appendix D. General changes include addressing the use of "should" instead of "must" for requirements; removal of provisions that are repetitive, outdated, or do not serve their intended purpose; changes for clarity and directness; changes that are reflective of actual practice; removal of provisions that are inconsistent with periodic reassessment of membership status; and reorganization to clearly delineate initial membership criteria from requirements for OPTN members to align with the OPTN Final Rule.

Staff then reviewed specific changes by Appendix section, starting with Appendix D.1, *Membership Requirements for Transplant Hospitals*, which includes minor changes to the transplant hospital geographic requirements and the addition of a requirement that transplant hospitals notify the OPTN in writing when the main hospital's address changes.

Staff described changes to the general section in D.2, *Designated Transplant Program Requirements*, and D.2.A, *Facilities and Resources*, which has been updated based on general OPTN Final Rule requirements and clarifying requirements for facilities. Staff described changes to D.2.B. *Transplant Program Key Personnel* and D.2.C. *Surgeon and Physician Coverage (Program Coverage Plan)*, including removal of the requirement for Transplant Program Director, consolidation of the provisions related to change in key personnel, removal of the requirement for a new primary to submit an assessment of all physicians and surgeons in a program, removal of the section that limits evaluation of a primary surgeon or physician's qualifications to when there is a change in primary, clarifying responsibilities of a program that does not

have all required key personnel, and reorganizing the program coverage plan requirements. Committee members asked questions prior to breaking into groups to discuss these provisions.

Summary of Discussion:

The Committee discussed the section of bylaws pertaining to temporary leave of individuals designated as primary surgeon or physician. Committee members questioned why temporary leave is defined as 30 days or more, noting that this timeframe is too short for accommodating many types of medical leave, in particular placing undue burden on women taking maternity leave to reaffirm their qualifications upon returning. A member suggested medical leave should be a separate category from temporary leave. Another member questioned why a program might have to inactivate due to a temporary leave when there is a plan for the designated individual to return.

Staff clarified that the intent behind the 30-day timeline relates to the expectation that a primary is involved in the day to do day operations, and that if the primary is out for any reason the program needs to have someone else step into the role. Staff explained that the Committee can continue to discuss whether a 30-day time period is appropriate and emphasized the need for consistency in handling temporary leave regardless of the reason. Staff also highlighted that there is an option in the bylaws for reinstatement of a primary if they return within a year of leaving that is less burdensome than a full application, as it requires only submission of 3 letters. A member expressed support for defining temporary leave as 30 days or more, indicating that they would not be comfortable with a program going without a primary on site for more than 30 days. The Committee proposed development of a process for interim designation of a stand in primary when the designated primary takes temporary leave.

The remaining changes for Appendix D will be reviewed and discussed at a future meeting.

7. Performance Monitoring Enhancement Update

OPTN Staff reported out on aggregated data based on the January 2024 SRTR reports on programs flagged under the four new metrics included in the Performance Monitoring Enhancement (PME) bylaw proposal, updates to the post-implementation monitoring report, and updates on additional data results from the offer acceptance collaborative evaluation.

Aggregate January 2024 Flag Data

Staff reviewed a breakdown of data on the 83 programs flagged in January 2024, out of a total of 724 programs, and shared with the Committee that lung offer filters were launched on January 31, 2024, and filters for liver and heart will be implemented in the first half of 2024.

Post-Implementation Monitoring Report

Another staff member reviewed the improvements made to the post-implementation monitoring report based on feedback provided by the Committee during the November meeting. Improvements include language clarification, edits to target a less technical audience, better definitions of key terms, and additional figures for context.

Summary of Discussion:

Committee members asked questions about an analysis of the quality of organs in terms of utilization rate, and whether that is addressed in this report. Staff answered that this report does not, but there are others available that do, and that this issue will be looked at as part of the work of the Expeditious

Taskforce, which includes a research dashboard with non-use and non-utilization data. SRTR also offers data tools that allow stratifying trends out within data, including by KDRI.

The Chair recommended updating the report to highlight non-utilization by KDRI and ensure that we highlight factors that increase non-utilization rate, such as OPOs being more aggressive in pursuing every potential donor, which could be lost in messaging.

Offer Acceptance Collaborative

Staff gave an overview of updated data from the collaborative's evaluation to include the offer acceptance rate ratios and transplants during the pre-engagement and active-engagement parts of the collaborative. The Collaborative included 83 programs, representing all regions and a variety of offer acceptance rates and program sizes. The data highlighted the degree of improvement of offer acceptance rate ratios of programs participating in the collaborative versus the rates of the rest of the nation. To help evaluate potential unintended consequences, the number of transplants of collaborative participants was reviewed, which overall saw an increase on par with or greater than the rest of the nation.

Four key improvement drivers were identified during key informant interviews with programs with better-than-expected offer acceptance: defining and revising acceptance criteria, optimizing the response to organ offers, performing retrospective reviews, and strengthening the waitlist management process. Based on these drivers, collaborative participants completed several projects to identify areas for improvement.

A committee member recommended including the use of third-party procurement and new procurement technologies as an improvement tool for using more organs.

Staff highlighted the resources that came out of the collaborative, including an effective practices guide within the Enhance Transplant Program Performance Monitoring toolkit on the OPTN website, an offer acceptance improvement guide on the Collaborative Improvement site on the OPTN website, and an offer acceptance course playlist within the OPTN learning management system.

8. Report of Investigative Activities

Staff presented aggregate data on reports made to the Patient Safety team between October 2023-January 2024. Staff explained that instead of presenting just the prior month's data, in the spirit of continuous process improvement, staff altered the in-person MPSC meeting presentation to instead provide cumulative data since the last time in-person meeting. Staff will continue to provide monthly Reports of Investigative Activity as part of the monthly conference call meeting materials.

Staff showed cumulative data on the types of reports received by month and as a percentage of the total. Staff also provided data on reporter types and comparison of reports that were self-reported and those wherein the reporter was filing a complaint against another member. Finally, staff shared common themes in cases that staff closed without forwarding to the MPSC for review. Those themes were a referral to another team that performs routine monitoring of that issue, deviations in practice from what members are used to that are not out of compliance with OPTN obligations, and reports made by non-members that are not under the purview of the OPTN and are not patient safety issues. There were no comments or questions from the committee.

9. Compliance Issues

Compliance Consent Agenda

The Committee met in closed session and reviewed a consent agenda consisting of thirteen transplant programs that had undergone a focused desk review during this cycle. The Committee released nine of those programs from monitoring. Four program reviews were recommended for an additional review of compliance with Policy 15.2 *Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements* or Policy 11.3.B *Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old*. The Committee also reviewed three transplant programs for allocation errors. Two transplant programs were issued a Notice of Noncompliance, and one program review was placed on the discussion agenda. The Committee reviewed 18 case investigations this cycle, consisting of complaints or self-reported potential policy violations. The Committee issued 11 Notices of Noncompliance and closed six issues with no action. Additionally, the Committee reviewed document submission from one member that received a Notice of Noncompliance at the November 2023 meeting. After reviewing the submission, the Committee released the member from monitoring. In addition, the Committee reviewed three reported living donor events. All three events were reported on time and closed with no action.

The Committee voted to approve the consent agenda by a vote of 29 Yes, 0 No, and 1 Abstention.

The Committee also discussed several ongoing cases in closed session.

10. Performance Issues

Performance Consent Agenda

For transplant programs under review for lower than expected 90-day graft survival rates and 1-year graft survival conditional on 90-day survival rates, the Committee approved the continued monitoring of 19 transplant programs: four heart programs for 90-day graft survival, and three heart programs for 1-year conditional graft survival; one kidney program for 90-day, and four kidney programs for 1-year conditional; one liver program for 90-day, and one liver program for 1-year conditional graft survival; four lung programs for 90-day, and one lung program for 1-year conditional. Additionally, the Committee approved the release from monitoring of 11 transplant programs: three heart programs for 90-day graft survival, two heart programs for 1-year conditional; one kidney program for 1-year conditional; two liver programs for 90-day graft survival, two liver programs for 1-year conditional; and one lung program for 1-year conditional.

For transplant programs under review for functional inactivity, the Committee approved the continued monitoring of one pancreas program. The Committee also approved requesting an update from one pancreas program that voluntarily inactivated once it reactivates.

The Committee approved the consent agenda by a vote of 32 For, 0 Against, and 0 Abstentions. The Committee also discussed the details of five ongoing cases in closed session.

11. Offer Acceptance

Staff presented a review of the submissions reviewed for the offer acceptance metric from the November 2023 MPSC meeting. In the July 2023 PSR data, there were 38 cases reviewed. Fourteen cases were recommended to close with no action, and 24 cases were recommended for continued monitoring. The Committee members expressed concerns about the consistency in how these cases were being reviewed. It was decided that all cases would be assigned “skip a cycle” of monitoring to give programs time to implement their quality improvement plans. The Committee also requested additional information on reviewing cases going forward.

Staff then discussed how many cases from the July 2023 PSR were also identified in the January 2024 PSR data:

- 15 of the 38 cases identified in the July 2023 PSR were not identified in the January 2024 PSR data
    - 11 of 15 were not identified or in the yellow zone
        - 6 cases were recommended to close with no action
    - 4 of 15 were identified in the yellow zone
- 23 of the 38 were still identified in the January 2024 PSR
    - 7 cases were recommended to close with no action based on the strength of program responses

One additional program theme was noted: four of the five pediatric liver programs were recommended to close with no action. Reviewers commented on the challenges of the programs and that they may list candidates with relatively large acceptance criteria in hopes for the opportunity for a split liver offer.

In analyzing the reviewed cases, staff discussed some specific topics common throughout:

- Reviewer confidence in the plan for improvement
- Recent personnel changes
- Participation in the offer acceptance collaborative
- Listing candidates with patient-specific acceptance criteria
- Post-listing review of candidates
- Routine "top of the list" review
- Written guidelines for offer acceptance
- Use of offer filters (kidney only)
- Ongoing review of declined offers

Staff presented the number of times each topic was applicable and whether reviewers chose to continue to monitor or close the case based on these assessments. Another consideration was whether the member was identified in the January 2024 PSR.

Summary of Discussion:

Committee members discussed the importance of being consistent when reviewing these cases. One member suggested a scale to use to determine whether to close a case or continue to monitor. First review – Continue to monitor with quality improvement plan requests; second review – is the program improving, request some additional information; third review-request an informal discussion. Another committee member stated that certain criteria should be provided to the reviewers to help with making decisions until the committee has more experience reviewing these cases. If the member participated in the Offer Acceptance Collaborative, should that have a significant weight in the decision? She agreed that having a scale of 1st, 2nd, 3rd time being reviewed would be beneficial in making decisions.

One committee member stated that he is looking for guidance, not absolute rules, to review these cases. The programs may be confused as to why they are being flagged and what their responsibilities may be. He stated that some additional education on offer acceptance criteria would be beneficial. Another member said the committee should have standardized guidelines to use and not rely fully on

the SRTR data. Another member stated that having offer acceptance filters in place is crucial, i.e., kidney and liver (newly implemented). All organ groups should have filters to use.

A member asked if staff could provide some interim data on offer acceptance practices. Staff stated that we can look at raw OPTN data to show trends for offer acceptance practices. The data would not be risk-adjusted. Another member stated that geographic locations can affect offer acceptance practices and asked what the best way is to review and determine a course of action. Another member suggested the Committee look at outliers only by setting the expected threshold at a low level.

A member suggested that the Committee look at the total number of events, losses, etc. – what is the best way to handle small programs who are identified because of small numbers. Another member stated that offer acceptance identification happens quickly because the metric has one of year data.

A member suggested looking at why offers are turned down, i.e., donor size, HLA issues, etc. What refusal codes are used? This information could be useful to the MPSC when making decisions on case review. A staff member stated that the intent is to encourage programs to use organ filters. It is a balance between what organs a program is willing to accept versus organs they refuse for specific reasons. Organ acceptance criteria is available for all organs – at this time there are organ filters in place for kidney and liver.

A member stated that as the Committee reviews these cases and builds a history of program practices and responses, they may need to re-visit the offer acceptance criteria that the SRTR data currently uses and ensure that the intent of the metric is clear. Other members stated that filters may not solve all of the offer acceptance practices – may have factors that filters cannot always address i.e. organ size for the recipient when weight is a factor – obesity in younger patients.

After Committee discussion, staff proposed that future offer acceptance case packets will provide additional guidance in the staff summaries. Some proposed changes to consider:

- Include a table indicating the common case characteristics
- Confirm that a released program will not receive another inquiry for two PSR cycles
- For cases with continued monitoring, include whether the reviewers recommended closing or monitoring in the November review
- Based on discussions today, include suggested action based on case characteristics
- Reviewers can always disagree with the suggestion based on case facts

12. Estimated Glomerular Filtration Rate (eGFR) Update & Case Review

Staff provided a very brief update on the Committee's review of eGFR implementation. The MPSC sent inquiries to programs that submitted waiting time modifications for fewer than 20 percent of their candidates registered on the waiting list as Black or African American. The request asked for the template of patient notification letters and when the program sent them, a description of the process for evaluating patients, and the time and effort required to implement the policy. The 56 program responses are due March 8, 2024, and the Committee will review all responses and determine any appropriate next steps at its meeting on March 29, 2024.

13. Membership Issues

The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants and applications are presented to the MPSC members as either a consent or discussion agenda in closed session. The Committee reviewed and approved the consent agenda by a vote of 30 For, 0 Against, and 0 Abstentions.

The Committee considered the applications and other actions listed below and will ask the Board of Directors to approve the following recommendations during its June 16-18, 2024 meeting:

- Approve 1 Program Change from Conditional to Full Approval
- Approve 1 Medical Scientific Membership Renewal

The Committee also reviewed and approved 16 applications for changes in key personnel in Transplant Programs or Components and received notice of inactivated programs and OPO changes.

14. MPSC Education/Communication Initiatives and Policy Referrals

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

<u>Recommendations for Policy Improvements</u>

Staff outlined the process for the MPSC to recommend a policy change through a referral to the Policy Oversight Committee (POC) and to the appropriate OPTN policy-making committee. Prior to the formalized policy referral process, the MPSC would send informal recommendations to Committees for suggested work. Reasons that the MPSC may recommend a policy change include when the MPSC finds that a policy is no longer applicable, lacking necessary elements based on changes in practice, confusing to members, difficult to monitor or enforce, or can be improved to address known safety or efficiency concerns.

<u>Update on MPSC 2022 MPSC Recommendations</u>

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

- The recommendation to Organ Procurement Organization (OPO) Committee to address late turndowns and non-utilization due to duplicate acceptances which resulted in the "Modify Organ Acceptance Limit" proposal due for implementation in September 2024.
- The recommendation to the Ad hoc Disease Transmission Advisory Committee (DTAC) to clarify HIV results, which resulted in a concept paper that did not receive the necessary feedback and is therefore on hold.

There we no comments or feedback from the Committee.

Status of Policy Referrals

Staff updated the MPSC on the following policy referrals to the DTAC, Operations and Safety Committee (OSC), Data Advisory Committee (DAC), and OPO Committee:

- Standardize Reporting Information to Patient Safety Contacts (referred to DTAC)
    - This is currently out for 2024 Winter Public Comment.
- Clarify Requirements for Reporting Post-Transplant Diseases (referred to DTAC)
    - This is set for a two-phase approach for public comment in summer 2024 and winter 2025 cycles.
- Review Prohibited Vessel Storage Policies (referred to DTAC).
    - This effort cannot proceed without a modification to the current PHS Guidelines, and the CDC is not supportive of modifying for this purpose.
- Create a Centralized Vessel Storage Reporting Mechanism (referred to the OSC).
    - This item was approved by POC, however the Executive Committee did not support it and voted against approving the project in its current state.
- Add a pre/post transfusion field (referred to OSC)
    - The OSC agrees this item is important, however, the committee is looking for ways to integrate this into existing work instead of creating a project for one data element.
- Transportation events (joint referral to DAC and OSC).
    - The OSC has requested data about this topic to better understand the issues. The OSC is in receipt of this information and will be meeting to discuss it soon. DAC will be discussing this referral during their March in-person meeting.
- Consider Clarifying DCD Conflict of Interest Policies (referred to the OPO Committee).
    - "Clarify Requirements for Pronouncement of Death" is currently out for Winter 2024 Public Comment.
- Referral to clarify procurement team responsibilities in the recovery operating room (referred to the OPO Committee)
    - The OPO Committee has reviewed this referral and has agreed that it is within their purview and will take it on as a project. The OPO Committee has prioritized it behind two other projects that they have planned to work on.

Staff also informed the MPSC about another project that the OPO Committee is planning to work on regarding improving machine perfusion data collection, due to its relevance to previous Committee discussions. Staff inquired if Committee members would like to share any informal feedback on that project with the OPO Committee.

Summary of Discussion:

The discussion revolved around more granular machine perfusion data capture. A member commented that it would be ideal to ensure the OPTN is collecting data about the member who is perfusing the organ (OPO vs transplant hospital). A member notes it is also important to document the type of perfusion device to better differentiate attributes or trends between them. Another member adds that this is an emerging issue in the field and suggests that duration of perfusion should be captured. A member explained that it is the transplant hospital that primarily drives the use of perfusion technology and therefore, any data quality requirements should specify transplant hospital obligations in addition to the OPO's. Staff suggested that the OPO committee could provide a presentation to the MPSC regarding machine perfusion data collection once they have begun substantial work on that project. The committee expressed support for this idea.

Potential Policy Referrals

Staff discussed potential policy referrals with the Committee:

- Potential Policy Referral- Estimated Glomerular Filtration Rate (eGFR) Monitoring

Staff reviewed the eGFR implementation to date and the recommendation for referral from a committee member during the January 19, 2024, MPSC meeting. Staff presented options to further eGFR compliance monitoring including requiring programs have a documented protocol and consideration of the implementation of an eGFR calculator built-in to the OPTN Computer System. Staff noted that Minority Affairs declined to address the implementation of an eGFR calculator due to time constraints and community concerns, and further advised that if the MPSC chose to endorse this idea, a single calculator would have to be chosen.

Summary of Discussion:

A Committee member who has also served on the Kidney Transplantation Committee began by sharing the current barriers to eGFR automation. She shared that the Kidney Committee invited outside eGFR experts to weigh in due to the nuanced nature of the calculation and specialization needed. The science of eGFR calculation is ever changing and with that, the formulas are constantly being worked on and updated. In addition to the issue of constant maintenance a calculator would require, is the issue of choosing specific criteria and methods of calculation, such as the inclusion of creatine versus cystatin. This member was not in favor of automation of the eGFR and suggested that this referral should be sent to the Kidney Committee given the organ-specific nature. Another Committee member liked the idea of automation for the sake of uniformity but noted another challenge to consider is that there are no validated formulas for patients with just one kidney, and thus would not support automation. A member endorsed the previous sentiments and noted that medical decision-making should be left out of policy as much as possible.

Another member supported the proposal to require programs to maintain a written eGFR protocol and requested clarification about how this is currently monitored. Staff responded that the Site Survey team reviews the written protocols, interviews staff members to ensure familiarity, and requests eGFR documentation for patients in the survey sample. A member noted that regardless of automation, members should still be required to maintain a written protocol. When asked by staff if having a written protocol meets the monitoring needs of this policy, the Committee responded affirmatively and requested to refer the matter to the Kidney Committee and not the Minority Affairs Committee.

In consideration of the possibility of introducing new disparities to the system, the Chair then turned the discussion to consider a time in the future when there may no longer be race-based lab values to report to the system. Another member believed this issue will be extinguished in time; fewer and fewer patients should be impacted moving forward as race-neutral eGFR is adopted universally. A member responded that this policy does not have a sunset date and emphasized that this policy would still benefit patients who are referred for transplant well past receiving a qualifying eGFR score.

- Potential Policy Referral - Late Decline

Staff presented the next potential policy referral on late declines and explained that it has arisen out of the recent work of the MPSC Allocations Review Subcommittee in reviewing allocations out of sequence (AOOS). In most instances of AOOS that have been reviewed, OPOs are attempting to allocate hard-to-place organs, decrease cold ischemic time (CIT), or place organs after “late declines” by transplant programs. Late declines can have a significant impact on both CIT and organ discard rates. The subcommittee reviewed several data requests on the topic but struggled to decide on criteria for an

alternative review process with the data that is currently available, particularly regarding reasons for declining and refusal codes.

Staff presented a referral to recommend a review of potential data collection efforts around late declines to improve understanding of the problem and determine opportunities for better utilization. More data might be beneficial in tracking trends and enable the MPSC to see if there are outliers that can be addressed. A better understanding of the scope of the problem could benefit the work that the MPSC is doing on AOOS and might positively impact allocation efficiency and organ use.

Summary of Discussion:

A member began by asking if late declines are being addressed under the Expeditious Task Force work. Staff noted that there might be some similar work being discussed by the Task Force but there are no concrete plans at this time. The member added that in any data collection on late declines, it would be important to include both primary and secondary refusal reasons, noting that organs are typically declined for a primary reason other than extended cold-ischemia time, which should be the secondary refusal reason. Another member who participated in the Refusal Codes project work with the DAC informed that the DAC struggled to define 'late decline' particularly due to complications of organ-specific timing and recommends that the OPO Committee lead this work and strive to address each organ individually. Another member echoed this referral approach and added that documentation of late declines is further complicated by successful re-allocation efforts. An additional challenge presented is the reliability of the current refusal data due to differences in when the actual decline occurs versus when the refusal is entered in the match run. The member acknowledged that community practice varies regarding entering this data in the OPTN Computer System. Another member noted that the data is messy and subject to OPO practice variability.

A member weighed in expressing their skepticism that a referral would be sufficient to address the issue, identifying that this is a systematic problem with OPTN allocation policies, OPTN Computer System data collection deficiencies, and OPO/Transplant Hospital accountability. This member added that research and studies will help point in the right direction in addressing this issue. A member questioned whether this was the right time to remake a referral on this effort, given the recommendation for more information. Staff responded that a referral by the MPSC reinforces that the effort is a priority of the MPSC and that the policy-making committee who receives the referral can determine where to place it in its queue of work. Another member suggested that the MPSC refer this topic with guidance that the receiving committee start working on the organ with the least variability in late decline practice to refine their approach for organs with more complex or prolific late decline practices.

The discussion moved to consideration of placement efficiency and how to balance this with equity and access, noting that there may be necessary compromises for certain patient populations. In response, another member stated the point is that addressing late declines is about organ discard and might positively impact efficiency and equity.

Staff proposed to make this a more robust referral by including data the MPSC has reviewed and including Task Force Leadership on the referral so they are aware. The Committee agreed to share this discussion feedback as a referral to the OPO committee.

- Potential Policy Referral- Organ Chain of Custody

Staff presented the final potential referral as arising from multiple submissions to the OPTN Patient Safety Reporting Portal where chain of custody procedures on both sides of organ and vessel transportation might have prevented issues including increased CIT, organ decline, and delayed cross-

matching. Several case summaries were presented, and staff reported that similar cases continue to be submitted to the OPTN Patient Safety Reporting Portal for investigation. They highlight a potential opportunity for improved chain of custody procedures to be implemented.

Summary of Discussion:

The Chair began discussion by noting that there is an increase in these events due to the broader distribution of organs. The increased volume means there are more couriers moving organs and more opportunity for mistakes. A Committee member supported the need for these changes but wondered about the feasibility of requiring additional check-ins, which in turn would necessitate more auditing. Another member asked why the requirement for OPOs to use the OPTN Organ Labeling, Packaging and Tracking System was never rolled out to Transplant Hospitals, as this seems like an existing solution that may address this issue. Staff did not have the answer off-hand but noted that they would find out. Another member noted that their hospital already utilizes protocols for dealing with couriers and transportation, which help mitigate these issues and wonders if best practice guidance might suffice instead of a policy change. The Committee ultimately agreed that this issue should be referred to OSC.

- Additional Policy Referrals

Staff solicited additional referral suggestions. A member asked if an exception pathway for pediatric pancreas should be considered as an addition to the bylaws. Staff responded that this can be evaluated alongside other exception pathways in upcoming bylaw revision work that the MPSC is working on.

Evaluation Plan Expansion

Staff summarized the work being done to expand the Evaluation plan to encompass all OPTN Policy and Bylaw monitoring, which includes components beyond just site survey. Staff outlined next steps, including sharing the expanded draft with the MPSC and other relevant OPTN Committees, and encouraged members to reach out if they have feedback to share.

Educational Initiatives

Staff summarized the work of the Patient Safety Workgroup and showed the updates to the Patient Safety Webpage. There was no feedback from members on this item.

Ongoing Education

Staff reviewed the various community conferences happening in 2024 and encouraged MPSC members to reach out if they are interested in presenting on any MPSC work or have ideas on how to continue to leverage these platforms for ongoing community education.

Email Communication

Staff summarized past Chair topics and potential new topics including communicating with the other member when a patient safety event is reported to collaboratively resolve the issue, a reminder on internal and external labels on pumps, a best practice in dealing with challenges in accurately obtaining pediatric donor weight, and a reminder on the use of expired flush solutions.

Summary of Discussion:

The Chair wanted to add a note about best practice in DCD recovery communication, due to the many reports involving communication breakdown. She emphasized encouraging OPOs to have a clear pre-recovery huddle process to allow all teams to communicate their needs. Another member added that there is often a need for a coordinated communication timeout especially when working with multiple procurement groups, arranging transportation, etc. Another member concurred adding that there is also

a need for members to define and review response expectations for issues involving third party vendors. The member noted that their OPO spends extensive time in case reviews of events involving these partners, so it is imperative to ensure those groups understand the need to have a sound practice and quality improvement relationship in place.

A member suggested that there should be clarification about labeling pumps. Policy is not overtly clear about where these labels should go, and therefore community practice varies.

Another member suggested that the MPSC may consider sharing information about FDA reporting of perfusion device malfunction, especially when the organ is not utilized due to the malfunction. The HRSA representative responded that the FDA has not gotten a single report of this type and reminded everyone that this type of event should be reported directly to the FDA. A member later asked if the FDA would want members to submit old events involving third party devices, as it had not occurred to them to report these. HRSA staff said they cannot speak for the FDA, but indicated they would want to know about any event of the sort. As a counterpoint to concerns about the increase in perfusion companies and other third parties, and the reports of device failures, a member shared that their institution uses third party recovery and perfusion regularly and noted that it is important to acknowledge that the use of that technology has allowed for transplant of more organs than ever before.

MPSC Transparency

Staff reported that all these efforts are related to ways to increase the transparency of the MPSC and to provide more MPSC-related content to the community. Staff requested feedback on ways to improve transparency and any other related comments from the Committee.

Summary of Discussion:

A member summarized that the objective for transparency is sharing “themes.” The discussion continued with members acknowledging that participating in the MPSC work has allowed them to learn about issues and events that they never would otherwise have considered, and this benefits their home organization. Members expressed appreciation for the Chair email communications in pursuit of the transparency objective.

A member added that they believe that broader sharing of living donor events would benefit the community, even understanding that the information would need to be anonymized and presented as theme rather than providing individual case details. Another member expressed a desire for fictionalized accounts of events that might allow for distribution of event information to help the community.

Upcoming Meetings

- March 29, 2024, 2-5pm,ET, Conference Call
- Apr 23, 2024, 3-6pm, ET, Conference Call
- May 21, 2024, 2-5pm, ET, Conference Call
- June 28, 2024, 2-5pm, ET, Conference Call
- July 23-25, 2024, Detroit

Attendance

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

- **SRTR Staff**
  - Ryo Hirose*
  - Jonathan Miller*
  - Jon Snyder
  - Bryn Thompson*
- **UNOS Staff**
  - Anne Ailor*
  - Robert Albertson*
  - Stephanie Anderson*
  - Sally Aungier
  - Sandy Bartal*
  - Dawn Beasley*
  - Matt Belton
  - Tameka Bland*
  - Torry Boffo*
  - Tyrone Brown*
  - Jadia Bruckner*
  - Nadine Cahalan*
  - Elinor Carmona*
  - Laureen Edwards
  - Katie Favaro*
  - Liz Friddell*
  - Jasmine Gaines
  - Rebecca Goff*
  - Caroline Hales
  - Asia Harden*
  - Houlder Hudgins
  - Lee Ann Kontos*
  - Krissy Laurie
  - Amy Minkler*
  - Heather Neil
  - Delaney Nilles
  - Jacqui O'Keefe*
  - Rob Patterson*
  - Shawn Richman*
  - Liz Robbins Callahan*
  - Bronson Robertson*
  - Melissa Santos
  - Laura Schmitt
  - Sharon Shepherd
  - Courtney Skeen*
  - Sarah Stevenson*
  - Juanita Street*
  - Stephon Thelwell
  - Melissa Tisdale*
  - Marta Waris
  - Betsy Warnick
  - Tameka Watkins*

- Trevi Wilson*
- Claudia Woisard*
- Emily Womble
- Hobie Wood*
- Karen Wooten*
- Amanda Young*

- **Other Attendees**
  - Alden Doyle*
  - Stephanie Pouch*

*Attended virtually