OPTN

OPTN Membership and Professional Standards Committee Report to the Board of Directors

Zoe Stewart Lewis, M.D., Ph.D., M.P.H., Chair Scott Lindberg, M.D., Vice Chair November 29, 2023

The OPTN Membership and Professional Standards Committee (MPSC) is pleased to provide this report to the OPTN Board of Directors. This report reflects the MPSC's work from June 2023 – November 2023 and summarizes the Committee's project work, recommendations for policy and system improvements, and efforts to increase public disclosure on the MPSC's activities and lessons learned. The report also includes updates on staff-led initiatives to support OPTN monitoring activities and quality improvement efforts.

Some key takeaways and considerations include:

- The offer acceptance rate ratio transplant performance metric was implemented in July 2023
- The MPSC is proceeding with its work on developing new OPO performance metrics that will be supported by new data collection
- The MPSC Allocations subcommittee continues to evaluate new approaches to allocation monitoring with consideration for late declines
- Efforts to increase public disclosure, community education opportunities, and policy and system improvements
 - MPSC driven policy referrals are being worked on by policy making committees with some going to Winter 2024 public comment
 - The MPSC continues to share lessons learned and best practices with the community, but seeks the OPTN Board of Directors' consideration for a mechanism outside of the MPSC to share quality and event reporting data as shared in its December 2022 report to the Board
- Updates on monitoring activities and trends

Updates on Current Committee Projects

Transplant Program Performance Metrics Enhancements

In December 2021, the Board of Directors approved a proposal to enhance the transplant program performance monitoring system.¹ The new monitoring system involves four risk-adjusted measures related to the patient journey through the transplant process. The table below outlines the four new metrics and the implementation date associated with each metric.

¹ Enhance Transplant Program Performance Monitoring System, Notice of OPTN Policy and Bylaw Changes, OPTN, https://optn.transplant.hrsa.gov/media/q0ud4hlp/policy-notice_tx-prgm-performance-monitoring_dec-2021.pdf.

Table 1: New Transplant Program Performance Metrics and Implementation

Metric	Implementation
90-day graft survival hazard ratio	July 2022
1-year conditional on 90-day graft survival hazard ratio	July 2022
Offer acceptance rate ratio	July 2023
Pre-transplant mortality rate ratio	July 2024

Implementation of Offer Acceptance

In preparation for the offer acceptance rate ratio metric implementation in July 2023, staff developed a collaborative improvement project to share effective offer acceptance practices and help transplant programs utilize improvement activities to increase their offer acceptance rates. The collaborative launched in January 2023 with a kick-off conference, included six months of active engagement, and concluded in July 2023. The collaborative cohort was the largest OPTN collaborative to date and included 83 transplant programs from across the nation; 49 kidney, 17 heart, 12 liver, and 5 lung programs. Recordings of the virtual sessions from the kick-off conference as well as collaborative webinars are available to all OPTN members in the OPTN Learning Management System (known as UNOS Connect). Throughout the project, staff have provided the MPSC with updates and shared resources, effective practices, and feedback from the community. The <u>toolkit²</u> on the OPTN website was also updated with offer acceptance rate ratio resources.

At its November 2023 meeting, the committee discussed the review process for the offer acceptance cases and determined that the MPSC needs to have additional discussion about criteria for review and consistency.

Preparing for Pre-Transplant Mortality Implementation

Over the next few months, the MPSC will discuss similar plans to prepare the community for the implementation of the pre-transplant waitlist mortality metric through appropriate educational initiatives and development of the MPSC's review process for members identified for review. OPTN Contractor staff have conducted key informant interviews with high performing programs and will use the insights gathered to work with the Committee to produce educational materials. The Committee will also use the insights from the key informant interviews to inform the development of the review process for programs identified for higher than expected pre-transplant mortality.

Evaluation

To evaluate the impact of the new monitoring system, the Committee proposes to statistically examine approximately 125 different primary outcomes. Analysis of each metric is broken down into subgroups based on variables intended to capture risk-influencing patient or donor features, as well as key indicators of socioeconomic status and equity groups. Evaluation of the metrics will focus on trends in deceased donor utilization rates, rates of new waitlist additions, offer acceptance rates, pre-transplant mortality rates, and post-transplant mortality rates. Donor utilization rate was included to evaluate whether the goal of increasing transplants is being met rather than the number of transplants because

² Enhance Transplant Program Performance Monitoring Toolkit, OPTN, <u>https://optn.transplant.hrsa.gov/policies-bylaws/enhance-transplant-program-performance-monitoring/</u>.

the utilization rate adjusts for changes in the number of donors. At its November meeting, the Committee reviewed an initial analysis of select metrics in the post-implementation monitoring plan. The report showed no evidence of unintended consequences from the use of these metrics to date. Based on the Committee's recommendations, the report is in the process of being revised and will be posted upon completion.

The MPSC continues to evaluate the number of programs identified for review and qualitative insights from individual program interactions. During the MPSC's July 2023 meeting, the MPSC reviewed the data contained in Table 2 and 3 on the number of adult and pediatric flags under the recently implemented post-transplant metrics, the number of flags for the new implementation of offer acceptance, and the number of flags for pre-transplant mortality, if that metric had been implemented.³ The next round of new data will be available in January 2024.

Table 2: Number of Adult Flags for New Performance Metrics in the July 2023 Program SpecificReports

	Imp	lemented Metrics		Not Yet Implemented Metrics	Total
	90-day graft survival	1-year conditional graft survival	Offer acceptance rate ratio	Pre-transplant mortality rate ratio	
Heart	7	7	5	6	25
Kidney	5	8	14	0	27
Liver	4	3	8	1	16
Lung	6	1	4	2	13
Pancreas	1	0	1	0	2
Total	23	19	32	9	83

³ MPSC Meeting Summary, July 25-27, 2023, OPTN,

https://optn.transplant.hrsa.gov/media/safg1di3/20230725_mpsc_meeting_minutes_public-2.pdf.

	In	nplemented Metrics	Not Yet Implemented Metrics	Total	
	90-day graft survival	1-year conditional graft survival	Offer acceptance rate ratio	Pre-transplant mortality rate ratio	
Heart	3	3	1	2	9
Kidney	4	1	4	1	10
Liver	3	0	4	2	9
Lung	1	0	1	0	2
Pancreas	0	0	0	0	0
Total	11	4	10	5	30

Table 3: Number of Pediatric Flags for New Performance Metrics in the July 2023 ProgramSpecific Reports

The MPSC developed a process to review transplant programs identified under the offer acceptance rate ratio criteria and sent initial inquiries to members identified for review after its July 2023 meeting. The inquiry letter offered programs the opportunity to set up an educational session with staff to review information available in the OPTN Data Services Portal in the OPTN Computer System to evaluate their offer acceptance practices. Staff reviewed the tools with several programs and provided additional information about making changes to individual listing criteria, acceptance criteria, and offer filters for kidney programs. In addition, the OPTN released a dashboard to transplant programs following incorporation of the July SRTR program specific report data that provides hazard ratio data for each characteristic included in the SRTR risk adjustment model for the program's transplant recipients. This dashboard is available to all programs and is located in the OPTN Data Services Portal.

When setting the thresholds, the MPSC paid close attention to the number of programs that would potentially be identified for review. The Committee acknowledged commonly cited criticism of the previous performance monitoring system: that fear of being identified for review dis-incentivized transplant programs' utilization of marginal and high-risk organs. The new post-transplant outcomes thresholds were designed to continue to identify transplant programs that are clinically meaningful outliers and that may present a risk to patient health and public safety but would likely not identify as many programs as the previous thresholds. The number of programs identified for post-transplant reviews remains stable and represents about half of the number of programs identified for post-transplant transplant reviews under the previous performance monitoring system. The MPSC will identify additional programs for review as the new pre-transplant metrics are implemented.

OPO Performance Monitoring Enhancements

As noted in the June report to the OPTN Board of Directors, the MPSC spent considerable time discussing the scope and goals of this project.⁴ The MPSC reviewed OPTN authority, the recommendations of the OPTN Ad Hoc Systems Performance Committee, relevant portions of the OPTN

⁴ MPSC Report to the Board, June 2023, OPTN, <u>https://optn.transplant.hrsa.gov/media/lkunawmp/membership-and-professional-standards-committee-mpsc-report-to-the-board-june-2023.pdf.</u>

Strategic Plan, and the current state of OPO performance monitoring and data collection. Representatives from the Centers for Medicare and Medicaid Services (CMS) provided an overview of CMS' oversight of OPOs; the new CMS OPO outcome measures, including information on the data CMS uses for the outcome measures and how it is obtained and analyzed; and an update on the implementation process, particularly for OPOs that fall within Tier 2 and Tier 3 during the interim assessment years and the recertification cycle.⁵ Additionally, the MPSC continues to discuss the characteristics that differentiate OPOs that perform well from OPOs that do not perform well and the parts of the donation process with wide variation in OPO practice. Following these discussions, the MPSC endorsed the use of many of the principles used in the *Transplant Program Performance Monitoring Enhancement* project to guide evaluation of potential OPO metrics. The selected principles state the MPSC should use metrics that:

- measure activities that are clearly within OPTN authority,
- the member can impact,
- the member is responsible for,
- have a clearly desired outcome,
- are risk adjusted, and
- incentivize behavior that will increase transplantation.

Additionally, the MPSC supported consideration of additional data collection and development of new metrics that would comply with these principles and meet the needs of the OPTN. The MPSC agreed that any revisions to OPTN OPO performance monitoring activities should not duplicate the CMS system but at the very least should complement the CMS metrics.

The MPSC acknowledged the important role donor hospitals play and the need for donor hospital accountability in terms of timely referrals, referral rates, clinical support of patient, and planned donation conversations, and suggested holding transplant hospitals accountable for those elements and/or creating incentives for donor hospitals.

The MPSC also acknowledged the critical role transplant programs play in these processes and the challenges often caused by transplant program acceptance practices including late declines, consistently turning down offers, and differing expectations regarding communication, donor management and testing, procurement arrangements, etc.

Another key theme raised in different MPSC discussions is the importance of consistency, which can improve understanding, accuracy and timeliness during complex situations and help avoid conflict and potential safety issues. Extreme variation in practice also makes data collection more difficult. For these reasons, the MPSC strongly encourages the OPTN to streamline deceased organ donor assessments, which was recommended within the National Academy of Science, Engineering, and Medicine (NASEM) report, and other OPO practices where wide variation exists.⁶

The MPSC endorsed the formation of a workgroup that includes representatives from the OPTN MPSC, OPO, Data Advisory, Patient Affairs and Transplant Coordinators Committees. At its July meeting, the MPSC developed an initial charge to the workgroup to focus on defining standard processes and consistent definitions for essential data points for the portions of the donation process that precede

⁵ MPSC Meeting Summary, May 4, 2023. <u>https://optn.transplant.hrsa.gov/media/d5sf1py4/20230504_mpsc_meeting_minutes_public.pdf</u>. ⁶ National Research Council. 2022. Realizing the Promise of Equity in the Organ Transplantation System. Washington, DC: The National Academies Press. https://doi.org/10.17226/26364.

donor registration, specifically the referral to authorization phases, and develop proposal for new data collection.⁷ The new data collection will eventually support the development of metric(s) and any needed risk adjustment. The OPTN currently collects only limited data for these phases of the donation process. The MPSC asked the workgroup to develop a concept paper for Winter 2024 public comment.

The OPO Performance Monitoring Enhancement Workgroup met on August 17 and September 29. The workgroup chair provided an update to the MPSC on the progress of the workgroup at its November meeting. The workgroup is designing an OPO referral data capture module that incorporates logic, standard processes and consistent definitions. The OPTN will partner with electronic donor record vendors to incorporate the module into their systems. The resulting data will then be electronically transferred to the OPTN Computer System. The MPSC will release a concept paper during Winter 2024 public comment to get feedback on this concept, the proposed contents of the module and the logics that will be incorporated into the module. The MPSC will also request input on the potential for collecting data on in-hospital deaths from transplant hospitals that can be used to validate data submitted by OPOs as a demonstration project for future data collection from all donor hospitals.⁸

Allocations Subcommittee

We continue to see a significant increase in the number of allocations out of sequence identified for MPSC review. The subcommittee that was created to try to better understand the reason for the increase and identify activities to reduce the number of allocations out of sequence has continued its work over the last six months.

The MPSC reviews allocations out of sequence during its in-person meetings three times each year. At each meeting the MPSC reviews a certain number of OPOs and will review all allocation issues for each OPO that have been compiled over a one-year period. Table 4 below shows, on average, the number of total allocation cases reviewed at each in person MPSC meeting in 2017-2019, and the actual number of allocation deviations reviewed by the MPSC at the last six in-person meetings.

MPSC Review Period	Allocation Deviations
2017 (average per 3 meeting cycles)	125
2018 (average per 3 meeting cycles)	150
2019 (average per 3 meeting cycles)	125
February 2020 Meeting	166
July 2022 Meeting	500
October 2022 Meeting	820
February 2023 Meeting	758
July 2023 Meeting	795
November 2023 Meeting	1529

Table 4: Individual Allocation Deviations Reviewed by MPSC

*The MPSC changed its review processes during the COVID pandemic

⁷ MPSC Meeting Summary, July 25-27, 2023, OPTN,

https://optn.transplant.hrsa.gov/media/safg1di3/20230725_mpsc_meeting_minutes_public-2.pdf.

⁸ MPSC OPO Performance Monitoring Enhancement Work Group Meeting Summary, August 17, 2023, OPTN,

https://optn.transplant.hrsa.gov/media/4hmp40fj/20230817_mpsc-opo-performance-monitoring-enhancement-wg_meeting-summary.pdf.

In almost all instances, the Committee determined that OPOs were making reasonable efforts to allocate organs that were hard to place. Examples of challenges faced by these OPOs include increasing cold ischemic time (CIT), late declines by accepting transplant programs, and logistical challenges such as the timing of that day's last commercial flight out of the local airport.

The MPSC formed a subcommittee to further analyze data, particularly to evaluate whether any patterns or trends of these allocations out of sequence suggest OPOs were inappropriately prioritizing transplant hospitals within a close proximity to the OPO's donation service area. It is important to note the MPSC's work so far has not revealed any evidence of such activity. Most often, OPOs seem to allocate hard-to-place organs out of sequence to transplant programs with high utilization of similar organs. The MPSC is concerned that one unintended consequence of allocations out of sequence, which seem appropriate to increase utilization of organs, may be creating the perception of greater inequities in access to transplantation. The MPSC is also concerned that, as OPOs develop their own protocols and allocate out of sequence at different times and using different parameters, confusion and conflict may increase between members. The MPSC feels strongly that OPTN allocation policies should include a framework or guidance to help OPOs allocate hard-to-place organs and promote consistency within the system. The MPSC also believes creating consistent processes for deceased donor evaluation and testing is important, and that doing so will have a positive impact on the ability to develop consistent allocation practices for hard-to-place organs. The MPSC can appropriately review them.

Until such a framework exists within OPTN policies, the MPSC expects the number of allocations out of sequence it reviews to continue to increase. The MPSC is concerned about the MPSC's workload and the sustainability of the current process. The subcommittee continues to evaluate how to prioritize reviews to focus on the issues of greatest potential concern, and how the MPSC can improve its review processes to identify and assess those scenarios. Last Spring, the Committee focused its review on data to identify donor characteristics that would predict a higher likelihood that allocation out of sequence would be required to ensure that a kidney is utilized. Although some donor characteristics such as higher KDPI, DCD donors, increased age, presence of hypertension and certain causes of death appear to be more prevalent in donors whose kidneys were allocated out of sequence, there are a substantial number of donors with the same characteristics that are allocated in sequence and according to policy requirements. These findings emphasize that the circumstances leading to allocation out of sequence are multi-faceted and complex, supporting the need to incorporate a framework for allocation of harder-to-place organs in OPTN allocation policies and the need to increase data collection and revise programming to adequately monitor allocation activities.

At its August and November meetings, the Committee has been evaluating data on kidney late turndowns to further evaluate the impact of transplant programs' declines after acceptances, which may result in allocations out of sequence, and is considering when it might be appropriate to send an inquiry to a transplant program, in addition to the OPO. The Committee's review has highlighted the need for a consistent definition of "late decline" and increased data collection and programming to ensure the MPSC can identify each instance when a transplant program's behaviors contribute to allocations out of sequence or potential non-use of an organ.

Require Reporting of Patient Safety Events Project

The MPSC began work on this project in February 2023 and is submitting the proposal to the OPTN Board of Directors during its December 2023 meeting. The purpose of this project is to align OPTN members' patient safety event reporting requirements with the OPTN contractor's requirement to notify HRSA and MPSC leadership of specific, concerning patient safety events within, typically, 24 hours after the event was voluntarily reported. The MPSC believes required reporting is essential to ensure the MPSC can review potential issues of concern and to allow staff to report events to HRSA as required by the OPTN contract.

The proposal that went out for public comment included that members report certain events within a 24 hour period and included required reporting of when an organ arrives too late resulting in the intended candidate not receiving the organ or resulted in non-use, any sanction taken by a state medical board or professional body against a transplant professional working for an OPTN member, and evidence that is discovered of an attempt to deceive the OPTN or the Department of Health and Human Services (HHS). However, the post-public comment feedback and MPSC discussion determined members should have 72 hours to report and consensus could not be reached to support including these additional required reports at this time and the MPSC supported removing them in favor of moving the rest of the proposed required reporting forward for Board approval.^{9,10}

Recommendations for Policy Improvements

The MPSC maintains its commitment to acting on the lessons learned in confidential medical peer review setting through policy recommendations when applicable and appropriate. By formalizing the referral process with the OPTN Policy Oversight Committee, the MPSC is able to communicate recommendations for policy improvements directly to OPTN Committees. Operationally, these recommendations, or referrals, are discussed at the conclusion of each MPSC in-person meeting and are sent to the respective OPTN Committees with a two-month response window. The progress on the referrals from the February 16-17, 2023, meeting are outlined below:

Standardize Reporting Information to Patient Safety Contacts

In July, the Ad Hoc Disease Transmission Advisory Committee (DTAC) formed a workgroup to modify OPTN Policy 15.1 Patient Safety Contact. The workgroup was comprised of members from the DTAC, MPSC, Data Advisory Committee (DAC), Organ Procurement Organization Committee (OPO), and Transplant Administrators Committee (TAC). This multiple disciplinary group met monthly to develop the appropriate revisions and the DTAC voted on final policy language in November. This project is on track to proceed for Winter 2024 public comment.

Clarify Requirements for Reporting Post-Transplant Diseases

The DTAC intends to prioritize the project after the Patient Safety Contact project described above. This project will likely begin in early 2024.

⁹ MPSC Meeting Summary, September 27, 2023, OPTN,

https://optn.transplant.hrsa.gov/media/q2zmlhc1/20230927 mpsc meeting minutes public.pdf. ¹⁰ MPSC Meeting Summary, October 16, 2023, OPTN,

https://optn.transplant.hrsa.gov/media/1arnoe1z/20231016_mpsc_meeting_minutes_public.pdf.

Review Prohibited Vessel Storage Policies

The DTAC and the Operations and Safety Committee (OSC) are interested in modifying policy to permit the storage of HCV-positive vessels. However, the CDC is not supportive of modifying the 2020 PHS Guideline to permit such storage. Until a change in the PHS Guideline occurs, the OPTN is unable to review prohibited vessel storage policies.

Create a Centralized Vessel Storage Reporting Mechanism

Due to their existing workload, work on this referral began during their September 2023 in person meeting. The OSC is in favor of reviewing OPTN Policy 16.6 *Extra Vessels Transplant and Storage*, but would like to pursue this in collaboration with the transplant community. As such, the OSC is planning to develop a concept paper to engage the community on what challenges they are experiencing. To support this work, OPTN Contractor staff are compiling data to depict the current vessel challenges the system is experiencing.

Align Organ Packaging Labels with OPTN Policy Requirements

The OSC is evaluating opportunities to better align the requirements outlined in OPTN Policy 16.3.D *Internal Labeling of Extra Vessels* and OPTN Policy 16.3.F *External Labeling* with the required fields in the OPTN Organ Labeling, Packaging, and Tracking System. The Committee is hopeful that this can be done through a system enhancement and will not require public comment.

Consider Clarifying DCD Conflicts of Interest Policies

Starting in July 2023, the Organ Procurement Organization (OPO) Committee began working on revisions to OPTN Policy 2.15.F *Withdrawal of Life Sustaining Medical Treatment or Support* and OPTN Policy 2.15.G *Pronouncement of Death* to clarify responsibilities of individuals who are employed by both the OPO and recovery hospital. The OPO Committee voted on final policy language in November and this project is on track to proceed for Winter 2024 public comment.

The MPSC referred one new project during the July 25-27, 2023, meeting, which is outlined below:

Introduce Pre/Post Transfusion Field

OPTN Policy 2.6 *Deceased Donor Blood Type Determination* outlines the requirements for blood typing, but it does not specify if the donor blood draw occurs pre- or post-transfusion. When reviewing a patient safety portal submission, it was identified that this information was not required by policy and could result in ABO typing concerns if inaccurately communicated between the OPO and transplant hospital. After discussion, the MPSC felt that not requiring this information could cause a patient safety risk due to potential incompatibility between donor and recipient. The MPSC felt that standardizing this information would allow transplant programs to evaluate organ offers in a more efficient manner. The OSC agreed that this information would be valuable to collect and reduce the potential for information to be missed in the free text. The OSC is considering the possibility of including this data element onto an existing data collection proposal, as opposed to proceeding to public comment to add one new data element.

Increasing Public Disclosure

The MPSC continues to fully support efforts to increase public disclosure about MPSC reviews and share lessons learned with the community. Since December 2023, the MPSC has added a section to the OPTN website that highlights "MPSC Resources" that are publicly available. ¹¹ This page includes reports to the OPTN Board of Directors, community messages from the MPSC Chair, and links to additional monitoring resources from the SRTR and CMS.

At its December 2022 meeting, the OPTN Executive Committee granted the MPSC the authority to distribute messages about important findings from MPSC reviews.¹² Since then, the MPSC has shared three messages to the community:

- Donation after circulatory death (DCD) protocols and managing multiple organs (December 2022)¹³
- Reducing risk and ensuring patient safety (July 2023)¹⁴
- Implementation of the Offer Acceptance performance metric and other recommendations (October 2023).¹⁵

A fourth communication is being drafted in response to the discussions the MPSC had during its November 2023 meeting.

A complimentary page to the MPSC Resources site is the OPTN Compliance and Evaluation page which includes the OPTN Member Evaluation Plan, a process description of member monitoring, and educational resources for members undergoing OPTN monitoring.¹⁶

The MPSC has received feedback from the community that has been appreciative of the messages to the community, the MPSC Resource page, and the new performance metrics dashboard. Members would also like the MPSC to share presentations from conferences so that anyone could see them, not only conference attendees. One possible mechanism to share these presentations and provide the same opportunity for engagement is to host an annual webinar which could also be posted to the MPSC Resources page for the community. There is also a desire for a process map for events that are reported to the OPTN Patient Safety Reporting Portal and preliminary steps have been taken to develop more visual resources that can be shared.

Though the MPSC has a duty to protect information shared in the confidential medical peer review setting, the MPSC is providing additional updates to the OPTN Board of Directors regarding significant monitoring activities, including a closed session update at the Board of Directors' December 4, 2023, meeting. The MPSC recognizes that the broader community would like access to more information on member interactions and reports of patient safety events while acknowledging the importance of continuous process improvement for the OPTN. In its December 2022 report to the OPTN Board of

¹¹ MPSC Resources, OPTN, https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/mpsc-resources/.

¹² Executive Committee Meeting Summary, December 4, 2022, OPTN,

https://optn.transplant.hrsa.gov/media/emgbm4ao/20221204_excom_meeting-summary.pdf.

¹³ MPSC Chair Communication, December 2022, OPTN, <u>https://optn.transplant.hrsa.gov/news/an-important-message-from-the-mpsc-on-</u> donation-after-circulatory-death-dcd-protocols-and-managing-multiple-organs/.

¹⁴ MPSC Chair Communication, July 2023, OPTN, <u>https://optn.transplant.hrsa.gov/news/an-important-message-from-the-mpsc-on-reducing-risk-and-ensuring-patient-safety/</u>.

¹⁵ MPSC Chair Communication, October 2023, OPTN, <u>https://optn.transplant.hrsa.gov/news/an-important-message-from-the-mpsc-on-the-implementation-of-the-offer-acceptance-performance-metric-and-other-recommendations/.</u>

¹⁶ Compliance and Evaluation, OPTN, <u>https://optn.transplant.hrsa.gov/policies-bylaws/compliance-and-evaluation/</u>.

Directors, the MPSC highlighted its discussion around consideration for an alternative review framework and the MPSC urges the OPTN Board of Directors to consider a possible mechanism outside of the MPSC to provide quality data and event reporting within the OPTN.¹⁷

The MPSC continues to brainstorm at each in person meeting on additional resource opportunities that can be provided as outlined below in *Educational Efforts* and will update the community as they become available.

Patient Safety Education Workgroup

The Patient Safety Project aims to share information with the donation and transplant community to heighten awareness of safety, promote effective practices, and prevent future occurrences. The group developed a resource to describe the types of serious safety events the MPSC has reviewed, including common factors that can contribute to the transplant of the wrong organ or patient, and recommendations for improvements to avoid similar issues. This resource is in the design process and will be submitted for approval to be added to the OPTN website. In addition, the workgroup drafted case studies of safety situations. In July, staff asked for additional volunteers to continue to refine the case studies and determine the best way to disseminate these learnings to help drive continuous improvement.

Educational Efforts

MPSC and OPTN Contractor staff work together to share several presentations, posters, and other educational resources about MPSC-related activities with the community throughout the year. At each multi-day MPSC meeting, in addition to considering policy improvement topics to share with the POC, the MPSC also discusses educational resources and communications that would be beneficial to members. At this time, the MPSC considers what topics from the meeting are most pressing and relevant to be shared through the MPSC Chair messages to the community. Some topics may require a different approach for disseminating information to the community beyond those messages, which MPSC members and staff collaborate on following the in-person meeting conclusion.

Appendix A includes all MPSC-related posters and presentations that occurred over the past year.

¹⁷ MPSC Report to the Board, December 2022, OPTN, https://optn.transplant.hrsa.gov/media/ojenbrcm/20221205_mpsc_report-to-theboard.pdf

Monitoring Activities

The charts below detail the various types and outcomes of MPSC monitoring activities between June 2023 and November 2023. Additional information about monitoring processes is available at https://optn.transplant.hrsa.gov/governance/compliance/

As required by the OPTN contract, the MPSC receives a Report of Monitoring Activities prior to each multi-day MPSC meeting. The report provides additional data and information about monitoring activities and is included as Appendix B to this report.

Annual Review of MPSC Operational Rules

The MPSC uses operational rules to manage the Committee's workload and provide guidance to staff on how to process certain issues consistently. For example, rather than asking all Committee members to review every case, the MPSC determined that staff should assign cases to an ad hoc subcommittee of reviewers, and then assign cases to consent or discussion agendas for full Committee review, based on the ad hoc subcommittee's recommendations. Other operational rules may advise staff to close certain reviews with no action and only forward to the MPSC if a second event occurs, or to automatically place cases meeting certain criteria on a consent agenda with a specific and consistent recommended action, rather than posting it for an ad hoc subcommittee. The MPSC will consider new rules as needed and reapprove all existing rules on a yearly basis. The MPSC began reviewing operational rules annually at its October 2022 meeting. The ongoing review of operational rules makes it possible to consistently improve the MPSC's process and the impact on patients. The MPSC reviewed all operational rules at its November 2023 meeting, removing a previously approved rule regarding the review of compliance with lower respiratory SARS-CoV-2 testing on all lung donors. The MPSC approved the rest of the current operational rules as written and implemented an additional rule for review of living donor transplant recipients not registered on the waiting list prior to transplant.

Performance Reviews

References to performance reviews include transplant program outcome reviews, transplant program functional inactivity reviews, and OPO organ yield reviews. As outlined in the OPTN Bylaws, factors the MPSC considers when evaluating program or OPO performance includes but is not limited to the following:

- Has the program or OPO demonstrated a patient mix, based on factors not adequately adjusted for in the SRTR model, that affected its outcomes?
- Is there a unique clinical aspect of the program or OPO (for example, clinical trials being conducted) that explains the lower than expected outcomes?
- Has the program or OPO evaluated their performance, developed a plan for improvement, and implemented the plan for improvement?
- Has the program or OPO demonstrated improvement in their outcomes based on recent data?
- Has the program or OPO demonstrated an ability to sustain improvement in outcomes?

Transplant Program Outcome Reviews

As described in the *Transplant Program Performance Metrics Enhancement* project section above, in July 2022, the MPSC implemented two newly approved post-transplant performance metrics: 90-day graft

survival, and 1-year conditional on 90-day graft survival. Two pre-transplant metrics, offer acceptance rate ratio and pre-transplant waitlist mortality rate ratio, are being implemented in July 2023 and July 2024, respectively.

In July, the MPSC implemented review of programs based on the offer acceptance rate ratio metric. The MPSC approved a new questionnaire to collect information about programs' efforts to improve offer acceptance and requested specific data for each program under review. Staff added language in their letters offering an educational session to review available data reports with members identified as having a lower than expected offer acceptance rate ratio. Staff walked members through the OPTN Computer System data reports, reviewed offer filters for kidney programs, and reviewed organ acceptance criteria as ways for programs to specify the kinds of offers they want to receive for their patients. In addition to working with members under review, staff also provide a memo describing resources to programs that fall within the performance improvement or "yellow zone" of the metrics. Table 5 below shows the total number of submissions reviewed by the MPSC from June – November 2023; they do not reflect the number of individual programs under review, as a program may submit multiple reviews to the MPSC throughout the year's review cycles. The newly identified programs are included in the "send initial inquiry" category.

MPSC Action		Program Type					
	Heart	Kidney	Liver	Lung	Pancreas	Total	
Send initial inquiry	11	18	16	9	2	56	
Continue to monitor	23	18	9	10	1	61	
Skip a cycle	8	16	10	7	1	42	
Informal discussions (held)	0	0	0	0	0	0	
Informal discussions (offer pending)	1	0	0	0	0	1	
Peer visit	0	1	0	0	0	1	
Request to inactivate	0	0	0	0	0	0	
Released	4	13	6	1	1	25	

Table 5: Number of Transplant Program Outcome Submissions Reviewed

Functional Inactivity

As required by the OPTN Bylaws, Appendix L, Section D.10.C, the MPSC periodically reviews transplant program functional inactivity. Table 6 outlines the triggers for functional inactivity review if the program does not perform a transplant during the stated period:

Program Type	Inactive Period
Kidney, Liver or Heart	3 consecutive months
Lung	6 consecutive months
Pancreas (K/P)	Both of the following:
	1. Failure to perform at least 2 transplants in 12 consecutive months
	2. Either of the following in 12 consecutive months:
	 A median waiting time of the program's K/P and pancreas candidates that is above the 67th percentile of the national waiting time
	 The program had no K/P or pancreas candidates registered at the program
Stand-alone pediatric	12 consecutive months
transplant programs	

Table 6: Transplant Program Functional Inactivity Requirements

Table 7 shows the total number of functional inactivity submissions reviewed by the MPSC; they do not reflect the total number of programs under review. Some programs may have provided multiple submissions throughout the year. The MPSC's review cycle coincides with each of the MPSC's three multi-day meetings each year. With changes to the inquiries used for outcomes reviews, staff plan to propose revisions to the tools used in inactivity review.

Table 7: Number of Transplant Program Functional Inactivity Submissions Reviewed

MPSC Action						
WPSC ACTON	Heart	Kidney	Liver	Lung	Pancreas	Total
Send initial inquiry	1	0	1	0	0	2
Continue to monitor	0	0	0	0	5	5
Skip a cycle	1	0	0	0	0	1
Informal discussions (held)	0	0	0	0	0	0
Informal Discussions (offer pending)	0	0	1	0	0	1
Request to inactivate	0	0	0	0	0	0
Released	0	0	0	1	2	3

OPO Organ Yield

As required by the OPTN Bylaws Appendix B, Section 2, the MPSC identifies an OPO for review for lower than expected organ yield if all of the following criteria are met for any organ type or all organs:

- More than 10 fewer observed organs per 100 donors than expected
- A ratio of observed to expected yield less than 0.90.
- A two-sided p-value is less than 0.05

As the MPSC develops its plan for enhancing OPO performance metrics, this review process will adapt to implement any proposed changes.

These figures represent the number of submissions reviewed by the MPSC; they do not reflect the total number of OPOs under review. Some OPOs may have provided multiple submissions throughout the year. The MPSC's review cycle coincides with each of the MPSC's three in-person meetings each year.

MPSC Action	Heart	Kidney	Liver	Lung	Pancreas	Aggregate	Total
Send initial inquiry	0	0	0	0	0	0	0
Continue to monitor	0	1	1	0	0	0	2
Skip a cycle	0	0	0	0	0	0	0
Informal discussions (held)	0	0	0	0	0	0	0
Informal discussions (offer pending)	0	0	0	0	0	0	0
Peer visit	0	0	0	0	0	0	0
Released	0	1	1	0	0	0	2

Table 8: Number of OPO Organ Yield Submissions Reviewed

Compliance Reviews

References to compliance reviews include site surveys, investigations, and allocations reviews. As outlined in the OPTN Bylaws, the MPSC's evaluation of compliance issues typically includes but is not limited to the following:

- Does the issue pose an urgent and severe risk to patient health or public safety?
- Does the issue pose a substantial risk to the integrity of or trust in the OPTN?
- Did the member show evidence of corrective action upon learning of the potential violation?
- What is the likelihood of recurrence?
- Do patient medical records or other documentation provide sufficient detail to determine the presence of mitigating factors at the time the potential violation occurred?
- The member's overall OPTN compliance history

The table below summarizes the number of different compliance reviews and the number of MPSC actions taken based on the Committee's reviews, including direct interactions with members as a part of the MPSC's review. Descriptions of the review processes and additional details about the types of reviews are below.

	MPSC Action	Allocation		
		Reviews	Site Surveys	Investigations
Action	Close with no action	41	14	32
	Follow up survey	n/a	2	n/a
	Notice of Noncompliance	10	0	45
	Letter of Warning	0	0	2
	Probation	0	0	0
	Member Not in Good Standing	0	0	0
Interactions	Informal Discussions (held)	0	0	5
	Informal Discussions (offer pending)	0	0	1
	Interviews (held)	0	0	2
	Interviews (offer pending)	0	0	0
	Peer Visit	0	0	2

Table 9: Compliance Reviews and MPSC Actions

Allocation Reviews

Staff review the match run for every allocation that results in a transplant to ensure an appropriate candidate received the organ. The MPSC reviews each OPO member's allocation issues on a yearly basis in order to identify and evaluate potential trends or behaviors. The MPSC reviews other allocation issues, such as hospitals accepting an organ for one recipient but transplanting another, on a real-time basis. As noted in the Allocation subcommittee section above, the MPSC has noted a significant increase in the number of OPO allocations out of sequence (AOOS), and the Committee has formed a subcommittee to evaluate potential changes and improvements to the MPSC's review of allocations information to identify the most concerning patterns or trends.

Table 9 above notes 51 total allocation reviews for the year, which covers annual review for approximately two-thirds of OPOs. Each OPO's review can contain anywhere from 1 to more than 200 allocations out of sequence. In most cases, after reviewing the detail of each individual allocation, the MPSC closes the OPO's review with no action because the MPSC determined the OPO acted appropriately to place organs that were unlikely to be utilized due to logistical issues like family or donor OR time constraints, late declines by the initial accepting program, or travel issues. In November 2023, the MPSC conducted a review of 1529 allocations out of sequence instances along with corresponding member responses, leading to two notices of non-compliance issued to a transplant hospital and an OPO. Since February 2020, there have been a total of 18 notices of non-compliance for AOOS situations given to OPOs and 10 given to transplant hospitals. These cases encompass various issues, including unwarranted aggressive placement, communication errors, re-running liver match runs without donor changes, SLK sharing when ineligible, and OPOs' lack of responsiveness. Analysis revealed that individual AOOS monitoring alone does not deter members, resulting in a significant increase in such situations since February 2020. Additionally, monitoring both high and low-performing members with the same scrutiny blurs perspective; thus, pulling back monitoring from the highest performing members could serve as a compliance motivator. Lastly, the MPSC allocation subcommittee has discovered that 47% of AOOS kidney cases resulted from late turndowns, with reasons including candidate-related issues, organ-specific problems, positive crossmatches, and other unspecified factors. Further analysis is needed to understand this correlation better and what opportunities exist for future monitoring.

Site Surveys

Staff survey each transplant program and OPO approximately once every three years. If staff identify any non-compliances during the review, they apply a survey evaluation tool (SET) to determine whether to conduct a follow-up review of the applicable policies in approximately nine months. If the member appropriately addressed any areas of noncompliance on a follow up review, the review is closed with no action. If the member does not demonstrate improvement on the follow-up survey, staff will forward the survey findings to the MPSC for review. The MPSC typically requests an additional follow-up review and may issue a Notice of Noncompliance for continued failure to improve.

Table 9 above shows the number of total surveys reviewed by the MPSC for both OPOs and transplant programs, and the number of MPSC actions. The Monitoring Effectiveness Report in Appendix B describes compliance rates for policies reviewed during site surveys, and education and monitoring changes and system enhancements identified as a result of survey findings. It also reports the number of routine and follow up desk reviews performed each quarter and the outcome by OPOs, transplant program, and living donor component surveys.

The compliance trend with policies generally improves after the initial monitoring cycle, although the duration of this period varies based on policy complexity, especially in cases involving EMR updates, multiple hospital departments, or ambiguous language. Policies, such as vessel storage, often hit a compliance ceiling around 95% due to persistent challenges like human error, lack of technical support, and staff turnover. New policies typically face higher non-compliance risks and often require ongoing monitoring efforts. Compliance issues can often arise from factors beyond transplant programs' control, necessitating support from insurance companies and timely EMR updates. To help combat these trends and also support the members, the Site Survey team is now conducting continuous monitoring based on specific triggers and OPTN Waiting List management opportunities which was presented to the MPSC at its November 2023 meeting. Site Survey is looking to expand upon this approach while striking a balance between record availability, patient safety, and historical compliance rates which will include presenting to the OPTN Transplant Administrators Committee for their feedback.

Investigations

Staff receive reports directly through the Safety Situation and Living Donor Event sections of the OPTN Patient Safety Reporting Portal, as well as through the Member Reporting Line, fax, mail, media articles, and referrals from other staff, including Patient Services, Help Desk, and Policy and Community Relations. Staff saw a 26% increase in reports received between January 2023 and October 2023 over the same time period in 2022.

Investigative staff triage each report to assess the potential risk to patient safety or public health and determine if immediate intervention is needed. As noted in the "Require Reporting of Patient Safety Events Project" section above, staff escalate reports of certain events to MPSC leadership and HRSA as required by the "HRSA Criteria" and the OPTN contract. Staff investigate reports by sending inquiries and requests for information to applicable members and analyzing available information in OPTN systems. The investigation seeks to determine whether the report can be substantiated and whether a noncompliance with OPTN obligations, including any risk to patient safety, exists. Staff provide updates to MPSC leadership, HRSA and members of the MPSC as needed, for example, when significant clinical expertise is required to determine whether any patient safety risks or noncompliances exist. If the

investigation substantiates a noncompliance, staff forward the investigation results to the MPSC for review. If the investigation is unable to substantiate the report and/or determines no violation occurred, staff have historically closed the case and have not forwarded it to the MPSC for review.

In July 2023, staff presented the internal intake form used to triage cases for MPSC review. Committee members provided additional factors to consider when determining risk and other feedback. Staff incorporated Committee feedback and suggestions and presented the revised form to the Committee for review at their in-person meeting in October. Changes included the addition of histocompatibility errors for consideration of patient harm, consistent identification of referrals and reports that are not under the purview of the OPTN, and clearer directions on leadership notification of high-risk cases. The intake form will now be reviewed annually by the Committee to further support the MPSC's oversight.

Routine Review of All Investigative Activity

In late 2022, the MPSC established a process to review all investigative activity. Historically, the MPSC only reviewed reports when investigations revealed a potential noncompliance with OPTN obligations. Though staff would consult with MPSC members during the investigation, particularly for guidance on clinical matters pertaining to medical judgement and patient safety, the full Committee did not receive information about investigative activities that were not identified as a potential noncompliance or safety issue. Staff revised the process and expanded the scope to provide the MPSC with greater information about all reported events and to aid in its decision-making and oversight function.

Since establishing the monthly review of data and presenting it to the MPSC, staff identified that throughout 2023, the majority of reported events fell into the "Identification of Transmissible Diseases" category, examples of which include potential donor-derived disease transmissions and possible unintended hepatitis B or C positive transplants. "Deceased Donor Organ Procurement" was the next most common case type, which can include donor risk status identification and bringing expired medication to recovery. Additionally, in 2023, staff received multiple anonymous reports about member culture concerns.

This report is also meant to inform the Committee about events investigated that did not get referred for MPSC review. Examples of reasons why staff did not refer a case for MPSC review include an inability to substantiate the claim, the investigation showing the event was permissible by current OPTN policy, and lack of reporter follow-up with investigators. After review of the report, MPSC members may request to view a closed case for a more in-depth look at the issue, which Committee members have done twice since the implementation of this report. That additional review of one of these issues led to a Committee request that staff begin referring those specific case types to the Committee.

Membership Applications

The MPSC monitors compliance with OPTN membership requirements, including new member applications. Table 10 below summarizes the different types of applications reviewed from December 2022 through November 2023. A total of 676 applications were reviewed, showing an increase from the 617 reviewed from December 2021 to November 2022. While there was a drop in the number of transplant program key personnel applications from 418 to 387, there was a slight increase in almost all other application types, most notably in new program and component applications. The implementation of the new bylaw requirements for Vascular Composite Allograft (VCA) – Uterus transplant programs is a contributing factor to this increase.

The OPTN Board of Directors approved bylaws in December 2021 to establish membership requirements for uterus transplant programs. This included splitting the existing VCA – Genitourinary category into three new categories – Uterus, External Male Genitalia, and Other Genitourinary Organ, and establishing uterus-specific key personnel requirements.¹⁸

On April 17, 2023, all current member VCA – Genitourinary transplant programs received an application to reapply under these to be implemented bylaws. Applications were due by August 17, 2023, to ensure staff and the MPSC could review and process each application in time for the anticipated implementation date, which coincides with the Board of Directors review of these applications at the December 2023 meeting. A total of 7 VCA implementation applications have been recommended for approval by the MPSC and are included in the Membership Actions to be reviewed by the Board of Directors at the December 2023 meeting.

The increased volume of applications is primarily in types of applications requiring MPSC subcommittee review, so translated to a higher Membership application workload for committee reviewers.

¹⁸ Establish Membership Requirements for Uterus Transplant Programs, Notice of OPTN Policy and Bylaw Changes, OPTN, https://optn.transplant.hrsa.gov/media/gapkro1m/policy-notice_establish-membership-requirements-for-uterus-transplantprograms_december-2021.pdf.

Type of Application	Number
Transplant Hospitals and Programs	
New Programs and Components	36
Key Personnel Applications	387
Program and Component Conditional Approvals	7
Conditional to Full Approvals	20
Conditional Extensions	6
Program and Component Long Term Inactivation	38
Inactivation Extensions	12
Program and Component Reactivations	20
Program and Component Withdrawals	23
Transplant Hospital Withdrawals	3
Organ Procurement Organizations (OPOs)	
OPO Key Personnel Change Notifications	9
OPO Withdrawal	1
Histocompatibility Labs	
New Histocompatibility Lab	4
Histocompatibility Lab Key Personnel Changes	79
Histocompatibility Lab Withdrawals	5
Non-Institutional Members	
New Non-Institutional Members	7
Non-Institutional Membership Renewals	19
TOTAL	676

Table 10: Number and Type of MPSC Application Reviews

Additional Staff-Led Improvement Activities

Individual Member Focused Improvement

The Individual Member Focused Improvement (IMFI) initiative aims to help individual members improve using quality improvement tools and engagements custom designed for the member and their unique need. Following the completion of a three-year discovery and design phase during which staff completed several pilot projects with input from the MPSC, broader deployment of IMFI started on October 1, 2022. During Fiscal Year 2023, nine IMFI engagements were completed, and ten projects are still ongoing as of October 1, 2023. All IMFI activities continue to be conducted virtually, which has increased access and ability to run multiple projects at one time.

The improvement activities staff offer to members engaged in IMFI include:

- OPTN Computer System Data Services Portal Training: Staff facilitate education session(s) with the member team on the various data portal tools available and real-time troubleshooting with OPTN subject matter experts (SMEs)
- Process Mapping/Failure Modes and Effects Analysis/Root Cause Analyses and Corrective Action Plans: Staff process map and evaluate the member's requested process in a collaborative session during which potential failure points and recommendations for improvement are discussed.
- Peer Mentoring: Staff organize collaborative sessions between the member and peer mentors from the community with relevant experience; the member can ask peers questions and for feedback about their improvement project/goal and a variety of topics.

The improvement activities completed with each IMFI member are dependent on what is most appropriate and valuable for their improvement goal.

IMFI is offered as performance improvement support to those members who receive a letter indicating that they are in the established operational boundary for performance improvement (or "yellow") zone for the new post-transplant performance monitoring metrics. Six of the active projects as of October 1, 2023, were started following the member receiving the letter letting them know that their program is in the "yellow zone", and three new inquiries originated since October 1, 2023, as a direct result of their receipt of said letter.

Staff continue outreach at regional meetings and community conferences, with a number of accepted posters and presentations. IMFI was included in the Member Quality update at all OPTN Regional Meetings during the most recent meeting cycle and an IMFI poster, entitled "The OPTN's New Individual Member Focused Improvement Initiative" was presented and won second place at the NATCO Annual Meeting in August 2023.

The IMFI project staff continues to collect feedback from each participating member via survey following each of their improvement activities. The team also continues to iterate the IMFI project structure with every engagement based on the member feedback on what worked well, and what did not, with the hope of decreasing project duration and increasing implementation efficiency.

eGFR Webinar and Member Outreach

At its December 2022 meeting, the OPTN Board of Directors approved a process intended to improve transplant equity by backdating the waiting times of Black kidney candidates who were disadvantaged by previous use of a race-inclusive calculation to estimate their level of kidney function. The Board action requires all kidney transplant programs, starting January 5, 2023, and within one year, to identify those Black kidney candidates whose current qualifying date was based on the use of a race-inclusive eGFR calculation, and to determine whether a race-neutral eGFR calculation shows they should have qualified sooner to start gaining waiting time for a transplant (even if their waiting time has been based on a different qualifying standard, such as dialysis). Programs must then apply to the OPTN for a waiting time modification for such candidates. Staff are actively supporting OPTN members with education and additional resources including a collaborative webinar which featured effective practices.¹⁹

Staff have had proactively reached out to primary kidney program administrators last summer to establish a dialogue about their level of awareness and compliance with the eGFR policy requirements. Throughout these conversations, staff offered a range of available resources to support the administrators, while also assessing and documenting their progress towards achieving full compliance with OPTN Policy 3.7.D (*Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations*).

Beginning in early 2024, routine site surveys will include interviews with transplant hospital staff regarding eGFR policy requirements. The objective is to ensure staff awareness regarding the possibility of listing a patient earlier with a non-African American eGFR and their requirement to submit waiting time modifications to ensure that their candidates receive the appropriate wait time.

OPTN Donation after Circulatory Death (DCD) Lung Transplant Collaborative

The Collaborative Improvement team recently concluded an 8-month DCD lung transplant collaborative, which engaged twenty-nine lung programs focusing on increasing DCD lung transplantation. Participants worked on improvement projects within two key areas: optimizing internal transplant process and strengthening collaboration with OPOs. The overall aim of the project was to increase DCD lung transplants by 30% (n=113) during the active engagement period compared to the eight months prior (n=87). At the end of the project, the cohort surpassed the project aim and increased DCD lung transplant by 45% (n=126). The project concluded with an in-person Learning Congress, inclusive of both participating and non-participating programs, as well as OPOs, who came together to discuss opportunities, challenges, and share effective practices related to DCD lung transplantation. The recordings from the plenary sessions are available in the OPTN Learning Management System (known as UNOSConnectSM).

The MPSC appreciates the interest in its operations. We look forward to continuing to improve our Committee operations to provide effective oversight over OPTN members, while also helping members improve performance, to the benefit of transplant patients nationwide.

¹⁹ Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations, Notice of OPTN Policy and Bylaw Changes, OPTN, <u>https://optn.transplant.hrsa.gov/media/eempkchs/policy-notice_egfrwtmods_mac_ki.pdf</u>.

Appendix A: Posters and Presentations

Title	Presenter(s)	Type of Presentation	Conference/ Meeting	Description
Member Quality and MPSC Update	MPSC Members	Presentation	Summer 2023 Regional Meetings	Update at all eleven Summer 2023 Regional Meetings about the MPSC's policy proposal, Allocations Monitoring, and OPO Performance Monitoring.
Utilizing a Collaborative Improvement Model to Increase DCD Lung Transplantation	Collaborative Improvement (CI) Team	Poster	Transplant Management Forum	The CI team presented a poster about the framework of the OPTN DCD Lung Collaborative. In particular, the poster highlights how bringing transplant professionals together with a desire to improve in the same area can drive change and progress.
The Improving Patient Safety Portal and the OPTN Membership and Professional Standards Committee (MPSC): How you can report, what other members are reporting, and what the MPSC wants you to know	Emily Womble and Laura Stillion	Presentation	Transplant Management Forum	This presentation reviewed the tools staff use to collect patient safety event data, patient safety trends seen by the MPSC, and how to effectively respond to inquiries and other MPSC requests. Presenters provided examples of types of events to report, and those members do not need to report. Presentation also provided case examples.
Sharing Effective Practices to Improve Post- Transplant Outcomes	Tameka Bland, Amanda Young, Sharon Shepherd, Sam Settimio	Poster	Transplant Management Forum	This poster described the key informant interview process that took place leading up to the implementation of the MPSC's new post-transplant performance metrics. The poster shared the key themes pulled from the key informant interviews and the educational resource created for the community because of the information gathering effort.
The OPTN's Individual Member Focused Improvement (IMFI) Initiative	Amanda Young, and community members, Dr. A. Whitney Brown,	Virtual Presentation	Transplant Management Forum	This video presentation shared insights from community members who have participated in the IMFI Initiative. It shared

	Deborah Maurer, Heather Marshall, and Misael Tonacao			perspectives from both members whose programs were engaged in an improvement project with IMFI and peer mentors who served as community subject matter experts to help a member program with their improvement goal.
The OPTN's New Individual Member Focused Improvement Initiative	Jasmine Gaines	Poster Presentation (won second-place prize of all poster presentations)	NATCO Annual Meeting	The IMFI initiative serves as a resource to OPTN members who are interested in collaborating with the OPTN on a performance improvement project as well as provide a carved-out space to learn from each other. IMFI's goal is to continue to promote continuous improvement through strategic partnership, data driven insight and education. As OPTN Members identify areas for improvement, the IMFI team is available to help members move towards their goals by coaching and facilitating specific QAPI projects.
Effective Practices for Improving the Offer Acceptance Rate Ratio Performance Metric	Jasmine Gaines	Poster Presentation	Transplant Quality Institute	As a result of this project, the donation and transplantation community will be educated on the upcoming Offer Acceptance Rate Ratio performance metric and transplant programs will have an educational resource that provides effective practices to improve their Offer Acceptance Rate Ratios.
Update from MPSC	Dr. Scott Lindberg	Presentation	Transplant Quality Institute	The presentation provided an update on the work that the MPSC has done over the past year and highlighted various topics, such as the Transplant Program Performance Monitoring, the Required Reporting of Patient Safety Events Projects, Allocation Monitoring, and the development of OPO Performance Metric. The

				presenter also participated on a panel with the OPTN President and SRTR Executive Director.
MPSC Initiative: Sharing Lessons Learned with the Community	Laura Schmitt	Presentation	Transplant Quality Institute	The presentation highlighted the efforts made by the OPTN to increase transparency and share lessons learned with the transplant community. The presentation shared the new MPSC Resource page on the OPTN website, noted the MPSC conferences throughout the year, outlined the policy referral process and current referrals, and discussed the MPSC Chair Community Emails.

Appendix B: Monitoring Effectiveness Baseline Report

OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Contract:	HHSH250-2019-00001C
Task:	United Network for Organ Sharing
Item:	A140
Due:	10 business days prior to each MPSC multi day meeting
Submitted:	October 18, 2023

Monitoring Effectiveness Baseline Report

MONITORING EFFECTIVENESS BASELINE REPORT

PWS Excerpt:

United The Contractor shall measure effectiveness of the processes used to identify compliance, Network encourage improvement, and determine sanctions for The Contractor shall develop objective metrics to monitor effectiveness of Contractor processes Organ used to monitor OPTN members, identify compliance problems, encourage performance Sharing improvement, and determine sanctions. These metrics will be developed with input from the OPTN MPSC and provided to the COR for review and approval by the end of the base contract period. The Contractor shall revise the proposed metrics based on COR comments and resubmit to the COR within 20 business days of receipt of comments for approval. The Contractor shall submit a report by 40 business days after submission of final metrics that documents baseline metric evaluation for Contractor processes. This report will be updated for the COR and the OPTN MPSC and provided 10 business days prior to each in-person MPSC meeting. Performance Standards

a) Standard: Findings that warrant review of existing processes or development of new processes lead to proposals to change processes.

Table 1. Quantity of deceased donor organ allocations resulting in a transplant wherein a deviation of allocation policy occurred, by type of deviation and fiscal quarter during which the deviation took place, July 1, 2021 - June 30, 2023

July 1, 2021 Ju						
Fiscal Quarter	Actual vs Intended	Allocation Out of Sequence	Local Backup	Other	Clean	Total
FY2021 Q4	5 (0.06%)	<mark>680 (7.73%)</mark>	9 (0.1%)	87 (0.99%)	8016 (91.12%)	8797
FY2022 Q1	0 (0%)	<mark>632 (7.42%)</mark>	7 (0.08%)	72 (0.85%)	7804 (91.65%)	8515
FY2022 Q2	1 (0.01%)	<mark>805 (9.16%)</mark>	3 (0.03%)	80 (0.91%)	7898 (89.88%)	8787
FY2022 Q3	0 (0%)	<mark>853 (9.28%)</mark>	47 (0.51%)	110 (1.2%)	8182 (89.01%)	9192
FY2022 Q4	0 (0%)	<mark>923 (9.49%)</mark>	67 (0.69%)	82 (0.84%)	8649 (88.97%)	9721
FY2023 Q1	1 (0.01%)	<mark>1028 (10.62%)</mark>	54 (0.56%)	89 (0.92%)	8505 (87.89%)	9677
FY2023 Q2	2 (0.02%)	<mark>1203 (12.43%)</mark>	90 (0.93%)	77 (0.8%)	8307 (85.82%)	9679
FY2023 Q3	0 (0%)	<mark>1444 (13.65%)</mark>	90 (0.85%)	103 (0.97%)	8944 (84.53%)	10581

Table 1 shows the number of organ allocations resulting in a transplant that deviated from organ allocation policy between July 1, 2021 and June 30, 2023. Deviation types indicate how an allocation deviated from policy. Most deviations are allocations wherein an OPO chose to bypass a candidate on a match run ("Allocation Out of Sequence"). The "Other" category includes directed donations, allocations where the recipient was not on the match run, and any other type of deviation from organ allocation policy. Highlighted shows a consistent increase over time in the proportion of allocations that are out of sequence. As a result of this finding, the OPTN Membership and Professional Standards Committee (MPSC) has created a workgroup to look at the root causes of the uptick in allocations out of sequence as well as how to change MPSC review to mitigate the increase in this trend.

Table 2. Quantity of patient safety event cases processed by Compliance and Safety Investigators, subsetby whether the case was referred to the MPSCApril 1, 2023 - September 30, 2023

Fiscal	Total number	Number of cases where investigators are still determining whether to refer to the		where investigators determined to the MPSC, and whether the ed
Quarter	of cases	MPSC	Referred	Not referred
FY2023 Q3	160	76 (47.5%)	12 (7.5%)	72 (45%)
FY2023 Q4	149	125 (83.89%)	1 (0.67%)	23 (15.44%)

Table 2 shows the number of patient safety event cases processed by Compliance and Safety Investigators (CSIs) between April 1, 2023 and September 30, 2023, and whether cases were referred to the MPSC. This timeframe was chosen to align with recent improvements to data collection processes which began in early 2023. Cases can take months to process, and a large proportion are still being processed at a point where it hasn't yet been determined whether to refer the case to the MPSC.

Table 3. Proportion of member touchpoint survey respondents who answered "Agree" or "Strongly Agree" when asked to answer whether they Strongly Disagreed, Disagreed, Agreed or Strongly Agreed with the following statement about their touchpoint: "The process helped us identify areas of improvement.", July 1, 2021 - June 30, 2023

	Respondent's answer		Total
Fiscal Quarter	Agree or strongly agree	Disagree or strongly disagree	Responses
FY2021 Q4	21 (100%)	0 (0%)	21
FY2022 Q1	15 (93.75%)	1 (6.25%)	16
FY2022 Q2	17 (94.44%)	1 (5.56%)	18
FY2022 Q3	15 (100%)	0 (0%)	15
FY2022 Q4	21 (100%)	0 (0%)	21
FY2023 Q1	19 (100%)	0 (0%)	19
FY2023 Q2	15 (100%)	0 (0%)	15
FY2023 Q3	16 (94.12%)	1 (5.88%)	17

Table 3 indicates the distribution of responses that OPTN touchpoint survey respondents provided when asked whether they strongly agreed, agreed, disagreed, or strongly disagreed with the following statement about their touchpoint "The process helped us identify areas of improvement." This includes the following touchpoints that occurred between July 1, 2021, and June 30, 2023: site survey, informal discussion, interview, hearing, and peer visit. The overwhelming majority of survey recipients answer that they agree or strongly agree with that statement.

Member			N	Total	Were records/el compliant?	ements
type	Organ	Policy	Type re	cords/elements	Yes	No
Fransplant	HR	6.1	Records	1104	1086 (98.37%)	18 (1.63%)
Recipient		6.1/6.2/6.3/6.4 DEE	Records	2039	1952 (95.73%)	87 (4.27%)
		6.2	Records	396	396 (100%)	0 (0%)
		6.4	Records	572	572 (100%)	0 (0%)
	KI	<mark>3.6.C</mark>	<mark>Records</mark>	<mark>12</mark>	<mark>6 (50%)</mark>	<mark>6 (50%)</mark>
		5.3.C	Records	636	606 (95.28%)	30 (4.72%)
		8.3	Records	1385	1352 (97.62%)	33 (2.38%)
		8.3 DEE	Records	1364	1327 (97.29%)	37 (2.71%)
		8.4.A	Records	1059	1043 (98.49%)	16 (1.51%)
		8.4.D	Records	85	84 (98.82%)	1 (1.18%)
		<mark>8.4.F</mark>	<mark>Records</mark>	<mark>328</mark>	<mark>299 (91.16%)</mark>	<mark>29 (8.84%)</mark>
		8.4.G	Records	96	96 (100%)	0 (0%)
		8.4.G DEE	<mark>Records</mark>	<mark>103</mark>	<mark>94 (91.26%)</mark>	<mark>9 (8.74%)</mark>
	LI	16.6.B Destroying	Records	9691	9650 (99.58%)	41 (0.42%)
		16.6.C Reporting	Records	<mark>9691</mark>	<mark>9102 (93.92%)</mark>	<mark>589 (6.08%)</mark>
		9	Records	2105	2002 (95.11%)	103 (4.89%)
		9.1.A/9.1.B/9.1.C/9.2	Records	332	325 (97.89%)	7 (2.11%)
		9.6/9.2	Records	1753	1726 (98.46%)	27 (1.54%)
		<mark>9.9.B</mark>	<mark>Records</mark>	<mark>231</mark>	<mark>215 (93.07%)</mark>	<mark>16 (6.93%)</mark>
	LU	10.1 DEE (listings)	Records	1148	1101 (95.91%)	47 (4.09%)
		10.1 Listings	<mark>Records</mark>	<mark>1258</mark>	<mark>1092 (86.8%)</mark>	<mark>166 (13.2%)</mark>
		10.1.A/10.1.B/10.1.C (LU, peds) (Listings)	Records	<mark>35</mark>	<mark>32 (91.43%)</mark>	<mark>3 (8.57%)</mark>
	PA	11.3.B	Records	486	476 (97.94%)	10 (2.06%)
		11.3.B DEE	Records	460	448 (97.39%)	12 (2.61%)
	Non-	<mark>15.2</mark>	<mark>Records</mark>	<mark>3296</mark>	<mark>2350 (71.3%)</mark>	<mark>946 (28.7%)</mark>
	specified	15.3.B	Records	1538	1468 (95.45%)	70 (4.55%)
		<mark>15.3.C</mark>	Records	<mark>3013</mark>	<mark>2197 (72.92%)</mark>	<mark>816 (27.08%</mark>
		18.1 Accuracy (TRF 6 mos)	Records	<mark>1224</mark>	<mark>460 (37.58%)</mark>	<mark>764 (62.42%</mark>
		18.1 Timely (TRF 1 year)	<mark>Records</mark>	<mark>15403</mark>	<mark>11691 (75.9%)</mark>	<mark>3712 (24.1%</mark>)
		18.1 Timely (TRF 2 years)	<mark>Records</mark>	<mark>14075</mark>	<mark>10652 (75.68%)</mark>	<mark>3423 (24.32</mark> %
		18.1 Timely (TRF 6 mos)	<mark>Records</mark>	<mark>15826</mark>	<mark>12210 (77.15%)</mark>	<mark>3616 (22.85</mark> %
		18.1 Timely (TRR)	<mark>Forms</mark>	<mark>17392</mark>	<mark>13877 (79.79%)</mark>	<mark>3515 (20.21</mark> %
		3.2	Records	2143	2116 (98.74%)	27 (1.26%)
		3.5 (NOL)	Records	1599	1537 (96.12%)	62 (3.88%)
		<mark>3.5 (NOR)</mark>	Records	<mark>401</mark>	<mark>375 (93.52%)</mark>	<mark>26 (6.48%)</mark>
		3.9	Records	2394	2379 (99.37%)	15 (0.63%)
		5.8.B	Records	5079	4893 (96.34%)	186 (3.66%)
OPO		15.4.A	Records	595	578 (97.14%)	17 (2.86%)
		16.5	Records	595	590 (99.16%)	5 (0.84%)

Table 4. Transplant recipient program, living donor program, and organ procurement organization policycompliance rates, subset by policy and associated organ type,July 1, 2021 - June 30, 2023

		18.1 (PTRs)	Records	65440	64722 (98.9%)	718 (1.1%)
		18.1 (Timeliness DDRs)	Records	13844	13777 (99.52%)	67 (0.48%)
		18.1 (Timeliness feedback)	Records	14485	14450 (99.76%)	35 (0.24%)
		18.1 (accuracy DDRs)	Records	308	308 (100%)	0 (0%)
		18.1 (noneligible)	Records	248	218 (87.9%)	30 (12.1%)
		2.11.B #2c [LI]	Records	406	404 (99.51%)	2 (0.49%)
		2.11.C #4 [HR]	Records	117	117 (100%)	0 (0%)
		2.11.D #5 [LU]	Records	81	81 (100%)	0 (0%)
		2.11.E #5 & #6 [PA]	Records	51	51 (100%)	0 (0%)
		2.13 #5	Records	355	355 (100%)	0 (0%)
		2.14.B	Records	595	581 (97.65%)	14 (2.35%)
		2.14.C #6	Records	595	582 (97.82%)	13 (2.18%)
		2.2 #14	Records	595	574 (96.47%)	21 (3.53%)
		2.2 #15	Records	625	619 (99.04%)	6 (0.96%)
		2.2 #2	Records	595	595 (100%)	0 (0%)
		2.2 #5	Records	595	595 (100%)	0 (0%)
		2.3	Records	585	585 (100%)	0 (0%)
		2.4	Records	595	595 (100%)	0 (0%)
		2.5	Records	595	593 (99.66%)	2 (0.34%)
		2.6.B	Records	147	144 (97.96%)	3 (2.04%)
		2.8 #7	Records	591	586 (99.15%)	5 (0.85%)
		2.9 #1	Records	355	354 (99.72%)	1 (0.28%)
		2.9 #2	Records	595	595 (100%)	0 (0%)
		2.9 #3*	Records	119	119 (100%)	0 (0%)
		Accuracy of DonorNet	Elements	8400	8400 (100%)	0 (0%)
		Accuracy of Serologies	Records	610	605 (99.18%)	5 (0.82%)
Living Donor	LDK	<mark>13.4.A (LDK)</mark>	Records	<mark>94</mark>	<mark>81 (86.17%)</mark>	<mark>13 (13.83%)</mark>
		<mark>13.4.C (LDK)</mark>	<mark>Elements</mark>	<mark>1568</mark>	<mark>1306 (83.29%)</mark>	<mark>262 (16.71%)</mark>
		14.4.B	Elements	6028	5997 (99.49%)	31 (0.51%)
	LDL	14.4.C	Elements	714	699 (97.9%)	15 (2.1%)
	Non-	14.1.A	Elements	9035	8743 (96.77%)	292 (3.23%)
	specified	<mark>14.2.A</mark>	Elements	<mark>2884</mark>	<mark>2711 (94%)</mark>	<mark>173 (6%)</mark>
		14.3	Elements	32426	31425 (96.91%)	1001 (3.09%)
		14.4.A	Elements	22504	22321 (99.19%)	183 (0.81%)
		14.5.A/14.5.B	Elements	768	765 (99.61%)	3 (0.39%)
		14.5.C	Elements	385	385 (100%)	0 (0%)
		<mark>14.7</mark>	Records	<mark>734</mark>	<mark>693 (94.41%)</mark>	<mark>41 (5.59%)</mark>
		<mark>14.8.B</mark>	Records	<mark>535</mark>	<mark>426 (79.63%)</mark>	<mark>109 (20.37%)</mark>
		18.1 (Accuracy)	Elements	13445	13075 (97.25%)	370 (2.75%)
		<mark>18.1 (Timely)</mark>	Records	<mark>2874</mark>	<mark>2691 (93.63%)</mark>	<mark>183 (6.37%)</mark>

* Policy 2.9 #3 was retired on 3/1/21

Table 4 shows the quantity of the records or elements of transplant programs, living donor programs, and organ procurement organizations reviewed by site surveyors, by policy and whether the surveyor identified a record as

being compliant with policy. This includes records that were surveyed between July 1, 2021 - June 30, 2023. Highlighted are policies with a greater than 5 percent non-compliance rate. Targeted education and monitoring changes as well as system enhancements have been made to help increase compliance with low compliance policies. Some examples are described below:

OPTN Policy 3.6.C: Individual Waiting Time Transfers

We observed a low rate of compliance with this policy so we expanded our monitoring to a process review for all organ groups. By shifting the focus away from self-reporting and having a process in place to discuss this with all members we are providing a greater service for our members.

OPTN Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt

In addition to chart review, we also include a policy and process review with the member. Site survey collaborated with Professional Education to develop an educational webinar that is now available as a resource to the member.

OPTN Policy 8.5.F: Highly Sensitized Candidates

Site Survey submitted an educational referral and development request due to a high non-compliance rate for the CPRA Approval Form and feedback from members about the issues with the system. In response to the referral, the language on the form was updated to help members understand and comply with policy.

OPTN Policies 15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements and 15.3: Required Post-Transplant Infectious Disease Reporting and Testing

These policies were implemented in 2021 to align with the 2020 PHS Guidelines. We collaborated with Policy and Community Relations and Professional Education for external educational efforts including an FAQ and educational webinars. We continue to provide targeted education surrounding these policies as well as providing resources to members on the OPTN website.

OPTN Policies 13.4.A and 13.4.C

We observed a lower rate of compliance with these policies, so we expanded upon our current monitoring to add in a process review when we do not have a sample of KPDs in order to allow for discussion and education.

At kidney and liver programs with living donor components, we increased the number of fields reviewed for accuracy on LDRs, in order to expand member awareness of the quality of this data.

We continue to review policies with very high rates of compliance to decide if it is time to retire monitoring. During OPO surveys, members have historically demonstrated a high rate of compliance with the following OPTN policies: 2.9 Blood and urine cultures, 2.11.C Echocardiogram for deceased heart donors, 2.11.D Sputum gram stain for deceased lung donors, and 2.13 Fluid intake and output. We retired our monitoring of these policies but for blood and urine cultures required by Policy 2.9 we still monitor any post-procurement culture results under Policy 15.4. For OPTN Policy 2.14.B, our monitoring only includes the first four required elements of the policy so we expanded the monitoring to include the elements required to be verified when the intended recipient is known prior to organ recovery. This allows for an opportunity for discussion and education as well. We also added a process review for OPTN Policy 16.5, Verification and recording of information before shipping, to allow for an opportunity to educate about policy requirements. Additionally, at OPOs, we focused our monitoring of accuracy on DDRs to those fields that require source documentation or interpretation prior to data entry.

Other improvements made based on educational referrals:

Lung height and weight fields have been decoupled to help members enter accurate data. Pa02 values now allow a decimal point to allow for more accurate data entry.

			Did the OPTN MPSC recommend for a focused desk review?			
Member Type	Fiscal Quarter	Total	No	Yes		
Transplant Recipient	FY2021 Q4	52	31 (59.62%)	21 (40.38%)		
	FY2022 Q1	46	25 (54.35%)	21 (45.65%)		
	FY2022 Q2	57	28 (49.12%)	29 (50.88%)		
	FY2022 Q3	71	29 (40.85%)	42 (59.15%)		
	FY2022 Q4	78	34 (43.59%)	44 (56.41%)		
	FY2023 Q1	75	38 (50.67%)	37 (49.33%)		
	FY2023 Q2	46	21 (45.65%)	25 (54.35%)		
	FY2023 Q3	33	15 (45.45%)	18 (54.55%)		
ОРО	FY2021 Q4	5	3 (60%)	2 (40%)		
	FY2022 Q1	6	6 (100%)	0 (0%)		
	FY2022 Q2	6	6 (100%)	0 (0%)		
	FY2022 Q3	3	2 (66.67%)	1 (33.33%)		
	FY2022 Q4	5	3 (60%)	2 (40%)		
	FY2023 Q1	3	3 (100%)	0 (0%)		
	FY2023 Q2	6	6 (100%)	0 (0%)		
	FY2023 Q3	5	4 (80%)	1 (20%)		
Living Donor	FY2021 Q4	21	15 (71.43%)	6 (28.57%)		
	FY2022 Q1	15	10 (66.67%)	5 (33.33%)		
	FY2022 Q2	20	11 (55%)	9 (45%)		
	FY2022 Q3	20	10 (50%)	10 (50%)		
	FY2022 Q4	21	15 (71.43%)	6 (28.57%)		
	FY2023 Q1	26	18 (69.23%)	8 (30.77%)		
	FY2023 Q2	15	8 (53.33%)	7 (46.67%)		
	FY2023 Q3	11	7 (63.64%)	4 (36.36%)		

Table 5. Proportion of members which underwent a <u>routine site survey</u>, and based on those findings the OPTNMPSC either did or did not recommend that they participate in a focused desk review,July 1, 2021 - June 30, 2023

Table 5 indicates the number and proportion of transplant recipient routine site surveys which were performed between July 1, 2021 and June 30, 2023 and resulted in a recommendation from the MPSC to perform a follow-up desk review. Follow-up desks continue to be needed to ensure CAP effectiveness with new policies or changes in practice. Please note, follow-up focused desks can be as small as one policy reviewed or multiple policies for different programs. Each quarter, around 25% to 50% of transplant recipient and living donor program routine site surveys result in a recommendation for a focused desk review. OPO routine surveys typically do not result in a recommendation for a focused desk review.

Member Type	Fiscal Quarter	N Total programs surveyed	Did the OPTN MPSC recommence for an additional focused desk review?		
			Yes	No	
Transplant Recipient	FY2021 Q4	26	20 (76.92%)	6 (23.08%)	
	FY2022 Q1	22	19 (86.36%)	3 (13.64%)	
	FY2022 Q2	31	27 (87.1%)	4 (12.9%)	
	FY2022 Q3	27	20 (74.07%)	7 (25.93%)	
	FY2022 Q4	8	7 (87.5%)	1 (12.5%)	
	FY2023 Q1	25	17 (68%)	8 (32%)	
	FY2023 Q2	37	22 (59.46%)	15 (40.54%)	
	FY2023 Q3	35	24 (68.57%)	11 (31.43%)	
OPO	FY2022 Q2	1	1 (100%)	0 (0%)	
	FY2022 Q3	1	1 (100%)	0 (0%)	
	FY2023 Q2	3	3 (100%)	0 (0%)	
Living Donor	FY2021 Q4	10	10 (100%)	0 (0%)	
	FY2022 Q1	11	10 (90.91%)	1 (9.09%)	
	FY2022 Q2	17	15 (88.24%)	2 (11.76%)	
	FY2022 Q3	3	3 (100%)	0 (0%)	
	FY2022 Q4	1	0 (0%)	1 (100%)	
	FY2023 Q1	6	6 (100%)	0 (0%)	
	FY2023 Q2	10	8 (80%)	2 (20%)	
	FY2023 Q3	4	2 (50%)	2 (50%)	

Table 6. Proportion of members which underwent a <u>focused desk review</u>, and based on those findings the OPTNMPSC either did or did not recommend that they participate in another focused desk review,July 1. 2021 - June 30. 2023

Table 6 shows the proportion of focused desk reviews between July 1, 2021 and June 30, 2023 which resulted in either the MPSC recommending an additional follow-up focused desk review. Each quarter around 20% of transplant program focused desk reviews resulted in an MPSC or MQ recommendation for an additional focused desk review. During this timeframe zero OPO desk reviews resulting in an additional desk review. Typically, each quarter around 10% of living donor program desk reviews result in a recommendation for an additional desk review.

•	0	Se action within 12 mon		
July 1, 20	21 - June 30, 2023			
Year - Quarter	N members with a compliance issue resulting in an MPSC action	N members with a compliance issue resulting in an MPSC action and another within 12 months	N members with a compliance issue resulting in an MPSC action but no other action within 12 months	% of members with a compliance issue resulting in an MPSC action and another within 12 months
2021 Q2	25	11	14	44%
2021 Q4	29	9	20	31%

14

18

36%

38%

Table 7. Proportion of members with a compliance issue resulting in MPSC action that have anothercompliance issue resulting in MPSC action within 12 months

8

11

2022 Q1

2022 Q2

22

29

Table 7 shows the number of members between July 1, 2021, and June 30, 2023, who have a case reviewed by the MPSC that results in an MPSC action, including information on whether the member had another case review resulting in MPSC action within 12 months. This data addresses members with any compliance issue, not a repetition of the same issue or policy violation. MPSC actions and review are defined in the OPTN Bylaws Appendix L, and may include continued monitoring, confidential actions such as Notice of Noncompliance, or public adverse actions such as Probation or Member Not in Good Standing. The data ends in 2022 to allow a full 12-month period after the MPSC action.

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Table 8. Proportion of transplant recipient programs participating in at least two routine site surveys between July 1, 2016 and June 30, 2023 that increased, decreased or retained the same compliance rate from their 2nd-most-recent to their most-recent routine survey, by policy and whether the 2nd-most-recent survey resulted in a recommendation for a follow-up focused desk review

Member	Organ		Data	Yes desk rev	Yes desk review recommendation cohort			No desk review recommendation cohort		
Туре	Туре	Policy	Туре	Decrease	Same	Increase	Decrease	Same	Increase	 Yes % Increase - No % Increase
Transplant	HR	6.1	Records	4	24	5	8	65	6	8
Recipient		6.1/6.2/6.3/6.4 DEE	Records	<mark>11</mark>	<mark>4</mark>	<mark>21</mark>	<mark>34</mark>	<mark>28</mark>	<mark>36</mark>	<mark>22</mark>
		6.2	Records	0	8	1	0	29	4	
		6.4	Records	0	15	0	0	39	1	-2
	KI	3.6.C	Records	0	1	0	0	1	0	
		5.3.C	Records	7	47	9	5	52	5	6
		<mark>8.3</mark>	Records	<mark>17</mark>	<mark>34</mark>	<mark>35</mark>	<mark>19</mark>	<mark>91</mark>	<mark>29</mark>	<mark>20</mark>
		8.3 DEE	Records	14	49	23	14	86	38	-1
		8.4.A	Records	12	64	4	5	113	2	3
		<mark>8.4.D</mark>	Records	<mark>0</mark>	<mark>12</mark>	<mark>5</mark>	<mark>1</mark>	<mark>17</mark>	<mark>2</mark>	<mark>19</mark>
		<mark>8.4.F</mark>	Records	<mark>8</mark>	<mark>39</mark>	<mark>17</mark>	<mark>11</mark>	<mark>58</mark>	<mark>14</mark>	<mark>10</mark>
		8.4.G	Records	0	5	0	0	3	0	
		8.4.G DEE	Records	0	3	1	0	3	0	
	LI	16.6.B Destroying	Records	7	16	3	3	24	6	-7
		16.6.C Reporting	Records	8	3	15	11	6	16	9
		9	Records	11	6	27	30	11	52	5
		9.1.A/9.1.B/9.1.C/9.2	Records	4	31	1	5	69	5	-4
		9.6/9.2	Records	10	25	9	16	53	21	-3
		<mark>9.9.B</mark>	Records	<mark>3</mark>	<mark>11</mark>	<mark>3</mark>	<mark>3</mark>	<mark>11</mark>	<mark>0</mark>	<mark>18</mark>
	LU	10.1 DEE (listings)	Records	1	0	1	0	0	0	
		10.1 Listings 10.1.A/10.1.B/10.1.C	Records	0	0	2	0	0	0	
		(LU, peds) (Listings)	Records	0	1	0	0	0	0	
	PA	11.3.B	Records	1	0	0	0	0	0	
		11.3.B DEE	Records	0	1	0	0	0	0	
	Non-	15.3.B	Records	14	127	46	37	260	57	8
	specified	3.2	Records	9	130	10	14	311	11	3
		3.5 (NOL)	Records	20	97	31	50	233	53	5

		3.5 (NOR)	Records	6	72	23	16	176	44	4
		3.9	Records	12	126	9	13	281	29	-3
		<mark>5.8.B</mark>	Records	<mark>14</mark>	<mark>32</mark>	<mark>164</mark>	<mark>67</mark>	<mark>273</mark>	<mark>86</mark>	<mark>58</mark>
OPO		15.4.A	Records	1	3	2	5	14	5	
		16.5	Records	0	5	1	3	18	3	
		18.1 (PTRs)	Records	0	1	5	9	7	8	
		18.1 (Timeliness DDRs) 18.1 (Timeliness	Records	3	0	3	7	10	7	
		feedback)	Records	0	2	4	8	10	6	
		18.1 (noneligible)	Records	2	0	1	5	8	6	
		2.11.B #2c [LI]	Records	0	5	1	2	20	2	
		2.11.C #4 [HR]	Records	0	3	0	0	11	0	
		2.11.D #5 [LU]	Records	0	3	0	0	11	0	
		2.11.E #5 & #6 [PA]	Records	0	5	0	0	11	0	
		2.13 #5	Records	0	3	0	0	10	1	
		2.14.B	Records	0	4	3	4	19	1	
		2.14.C #6	Records	3	3	0	4	14	6	
		2.2 #14	Records	2	2	2	5	8	11	
		2.2 #15	Records	0	6	0	1	18	5	
		2.2 #2	Records	0	6	0	0	24	0	
		2.2 #5	Records	0	6	0	0	24	0	
		2.3	Records	0	6	0	0	24	0	
		2.4	Records	0	6	0	0	24	0	
		2.5	Records	0	5	1	1	21	2	
		2.6.B	Records	0	2	5	1	19	1	
		2.8 #7	Records	0	5	1	1	17	6	
		2.9 #1	Records	0	3	0	0	9	2	
		2.9 #2	Records	0	5	1	0	24	0	
		2.9 #3*	Records	0	3	1	0	15	0	
		Accuracy of Serologies	Records	1	3	3	1	22	1	
Living	LDK	13.4.A (LDK)	Records	1	8	1	1	3	1	
Donor		13.4.C (LDK)	Elements		2	5	1	2	1	

	<mark>14.4.B</mark>	<mark>Elements</mark>	<mark>7</mark>	<mark>61</mark>	<mark>24</mark>	<mark>7</mark>	<mark>75</mark>	<mark>11</mark>	<mark>14</mark>
LDL	<mark>14.4.C</mark>	<mark>Elements</mark>	<mark>2</mark>	<mark>8</mark>	<mark>2</mark>	<mark>0</mark>	<mark>18</mark>	<mark>7</mark>	<mark>-11</mark>
Non-	<mark>14.1.A</mark>	<mark>Elements</mark>	<mark>37</mark>	<mark>15</mark>	<mark>52</mark>	<mark>40</mark>	<mark>46</mark>	<mark>32</mark>	<mark>23</mark>
specified	<mark>14.2.A</mark>	<mark>Elements</mark>	<mark>23</mark>	<mark>44</mark>	<mark>37</mark>	<mark>34</mark>	<mark>71</mark>	<mark>12</mark>	<mark>25</mark>
	<mark>14.3</mark>	<mark>Elements</mark>	<mark>28</mark>	<mark>10</mark>	<mark>65</mark>	<mark>39</mark>	<mark>23</mark>	<mark>55</mark>	<mark>16</mark>
	14.4.A	Elements	25	24	55	25	42	52	9
	14.5.A/14.5.B	Elements	2	64	6	1	84	4	4
	14.5.C	Elements	0	72	0	1	88	0	-0
	<mark>14.7</mark>	Records	<mark>10</mark>	<mark>32</mark>	<mark>53</mark>	<mark>19</mark>	<mark>65</mark>	<mark>23</mark>	<mark>34</mark>
	18.1 (Accuracy)	<mark>Elements</mark>	<mark>38</mark>	<mark>21</mark>	<mark>45</mark>	<mark>58</mark>	<mark>23</mark>	<mark>37</mark>	<mark>12</mark>
	18.1 (Timely)	Records	20	56	28	25	72	22	8

Table 8 shows the quantity of pairs of all routine transplant recipient site surveys where the program had two routine site surveys between July 1, 2016 and June 30, 2023 where a specific policy was reviewed. It compares the compliance rate of the first (2nd most recent) and second (most recent) surveys within those survey pairs for those policies, and indicates whether those rates decreased, increased or stayed the same. It also divides survey pairs into two cohorts based on whether a pair's first survey resulted in a recommendation for a desk review. The eighth column of the table indicates the percentage point difference between cohorts in the proportion of survey pairs where compliance rate increased. Included and highlighted are policies where there were 10 or more total elements or records reviewed in each cohort, and there was a 10 point or larger difference between cohorts in the percentage of total surveys where there was an increase in policy compliance rates. For all such policies except 14.4.C, the cohort with a desk review between surveys had a greater percentage of increases in policy compliance rates than the non-desk review cohort.