

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

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*June 12, 2024*

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 December 2023 – May 2024 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 OPTN Contractor staff-led initiatives to support OPTN monitoring activities and quality improvement efforts.

Some key takeaways and considerations include:

- The pre-transplant mortality rate ratio performance metric will be implemented in July 2024
- The MPSC is proceeding with its work on revising membership bylaw requirements
- 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 public comment in upcoming public comment cycles.
  - 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.<sup>1</sup> 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.

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<sup>1</sup> 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](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**

<b>Metric</b>	<b>Implementation</b>
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
<i>Pre-transplant mortality rate ratio</i>	<i>July 2024</i>

### *Preparing for Pre-Transplant Mortality Implementation*

In preparation for the pre-transplant mortality rate ratio metric implementation in July 2024, OPTN Contractor staff performed key informant interviews with transplant hospitals whose programs have better-than-expected pre-transplant mortality rate ratios and developed a resource to share effective practices. The resource is available on the OPTN website on the Enhance Transplant Program Performance Monitoring toolkit page<sup>2</sup>. The MPSC is considering additional educational offerings on this metric prior to implementation, including an informational email from the MPSC chair and a virtual webinar.

The MPSC Performance Monitoring Enhancement Subcommittee is using the insights gathered through the key informant interviews to inform the development of the review process for programs identified for higher-than-expected pre-transplant mortality. The draft review process will be presented to the MPSC at its June 28, 2024 meeting for approval.

### *Evaluation*

To evaluate the impact of the new monitoring system, the Committee proposed 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 focuses 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 the utilization rate adjusts for changes in the number of donors. At its March 2024 meeting, the Committee reviewed an updated version of the 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. The initial analysis was updated based on feedback received from the Committee following its initial review of the analysis report at its November 2023 meeting.

The MPSC continues to evaluate the number of programs identified for review and qualitative insights from individual program interactions. During the MPSC's March 2024 meeting, the Committee reviewed the data contained in Tables 2 and 3 on the number of adult and pediatric flags under the recently implemented post-transplant outcomes and offer acceptance metrics and the number of flags for pre-

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

transplant mortality, if that metric had been implemented.<sup>3</sup> The next round of new data will be available in July 2024.

**Table 2: Number of Adult Flags for New Performance Metrics in the January 2024  
Program Specific Reports**

	Implemented 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	4	8	2	8	22
Kidney	7	8	13	0	28
Liver	9	0	5	4	18
Lung	5	1	3	1	10
Pancreas	2	0	1	0	3
Total	27	17	24	13	81

**Table 3: Number of Pediatric Flags for New Performance Metrics in the January 2024  
Program Specific Reports**

	Implemented 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	2	0	1	4	7
Kidney	2	1	4	1	8
Liver	4	0	3	1	8
Lung	1	0	0	0	1
Pancreas	0	0	0	0	0
Total	9	1	8	6	24

## Performance Monitoring Changes to Support OPTN Expeditious Task Force Initiatives

At its January 19, 2024 conference call, the Committee discussed a request from the OPTN Expeditious Task Force to consider a potential moratorium on post-transplant outcomes monitoring to support the Task Force's bold aim of 60,000 deceased donor transplants in 2026. The Expeditious Task Force noted that perceptions of risk for MPSC performance review associated with transplantation of higher risk donor organs constituted a barrier to transplant program acceptance of these organs. The Committee

<sup>3</sup> MPSC Meeting Summary, March 5–7, 2024, OPTN, [https://optn.transplant.hrsa.gov/media/safg1di3/20230725\\_mpsc\\_meeting\\_minutes\\_public-2.pdf](https://optn.transplant.hrsa.gov/media/safg1di3/20230725_mpsc_meeting_minutes_public-2.pdf).

communicated to the Task Force that they did not support a complete suspension of review of all post-transplant outcomes but suggested consideration of changes to the thresholds for review, risk adjustment model improvement, and additional education efforts on risk adjustment and the effect of acceptance of higher risk organs on programs' post-transplant outcomes metrics. At its March 25, 2024 meeting, the Executive Committee formally requested that the MPSC consider revising the post-transplant outcomes criteria to capture less programs to remove a barrier to increased transplants and increase the offer acceptance criteria to create a stronger incentive for transplant programs to accept organs.

When setting the thresholds for the enhanced transplant performance metrics, 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 reviews under the previous performance monitoring system. With the addition of the offer acceptance metric in July 2023 and the upcoming implementation of the pre-transplant mortality metric, the number of programs identified overall by all four metrics is expected to be about the same as were identified under the previous one-year post-transplant patient and graft survival metric.

At its April 23, 2024 conference call, the Committee reviewed data on post-transplant outcomes reviews since the implementation of the new metrics and metric criteria in July 2022 and Jon Snyder, Director, Scientific Registry of Transplant Recipients (SRTR), provided information on the effect of threshold changes on the number and characteristics of programs identified and no longer identified. Dr. Snyder presented example changes to criteria, including a change from the current criteria of 50% probability of a program's hazard ratio being 1.75 or above to 2.0 or above for the two post-transplant outcomes metrics and a change from the current criteria of 50% probability of a program's rate ratio being 0.30 or below to 0.35 or below for offer acceptance metric. The Committee requested a literature review to determine if there is evidence that a change in MPSC post-transplant outcomes criteria affects acceptance behavior of transplant programs. The Committee also supported further consideration of potential changes to the criteria for the two post-transplant outcomes metrics and the offer acceptance metrics at its upcoming meetings on May 21 and May 29, 2024.

## OPO Performance Monitoring Enhancements

As noted in the June 2023 report to the OPTN Board of Directors, the MPSC spent considerable time discussing the scope and goals of this project.<sup>4</sup> The MPSC reviewed OPTN authority, the recommendations of the OPTN Ad Hoc Systems Performance Committee, relevant portions of the OPTN 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

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

implementation process, particularly for OPOs that fall within Tier 2 and Tier 3 during the interim assessment years and the recertification cycle.<sup>5</sup> Additionally, the MPSC discussed 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.

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 endorsed the formation of a workgroup including representatives from the OPTN MPSC, OPO, Data Advisory, Patient Affairs and Transplant Coordinators Committees. At its July 2023 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 donor registration, specifically the referral to authorization phases, and develop proposal for new data collection.<sup>6</sup> 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, 2023. 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 had planned to 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 would be incorporated into the module. The MPSC's concept paper also requested input on the potential for collecting data on in-hospital deaths from transplant hospitals that can be

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<sup>5</sup> MPSC Meeting Summary, May 4, 2023. [https://optn.transplant.hrsa.gov/media/d5sf1pv4/20230504\\_mpsc\\_meeting\\_minutes\\_public.pdf](https://optn.transplant.hrsa.gov/media/d5sf1pv4/20230504_mpsc_meeting_minutes_public.pdf).

<sup>6</sup> MPSC Meeting Summary, July 25-27, 2023, OPTN, [https://optn.transplant.hrsa.gov/media/safg1di3/20230725\\_mpsc\\_meeting\\_minutes\\_public-2.pdf](https://optn.transplant.hrsa.gov/media/safg1di3/20230725_mpsc_meeting_minutes_public-2.pdf).

used to validate data submitted by OPOs as a demonstration project for future data collection from all donor hospitals.<sup>7</sup>

At its meeting on January 16, 2024, the OPTN Executive Committee postponed the release of the MPSC's concept paper at the request of Health Resources and Services Administration (HRSA) to avoid confusion between the concept paper and an expected U.S. Department of Health and Human Services (HHS) Secretarial Directive. The HHS Secretarial Directive was expected to include a directive that the OPTN collect data on ventilated referrals that overlaps with the potential data collection described in the concept paper. Members of the OPTN Data Advisory Committee (DAC) and two OPTN workgroups have offered recommendations to HRSA regarding this Directive. The OPO Performance Monitoring Enhancement Workgroup, at the request of HRSA through the DAC, met three times in December and January to review and develop feedback on a draft ventilated referral data collection form for potential inclusion in the HHS Secretarial Directive. The OPO Performance Monitoring Workgroup Chair and DAC leadership provided the MPSC Workgroup's and the DAC Pre-Waitlist Data Collection Workgroup's feedback to HRSA on January 31, 2024. The HHS Secretarial Directive was received by the OPTN on February 5, 2024. The OPTN Executive Committee resolved to discuss next steps for the MPSC's concept paper following release of the 60-day Federal Register notice of an Information Request Package (ICR) for the federal Office of Management and Budget (OMB).

## 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 meetings three times each year. At each meeting, the MPSC reviews a specific number of OPOs and examines all allocation issues, excluding applicable operational rules, for each OPO compiled over the past year. Table 4 below shows, on average, the number of total allocation cases reviewed at each in person MPSC meeting from 2017-2019, and the actual number of allocation deviations reviewed by the MPSC from the corresponding meeting.

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<sup>7</sup> MPSC OPO Performance Monitoring Enhancement Work Group Meeting Summary, August 17, 2023, OPTN, [https://optn.transplant.hrsa.gov/media/4hmp40fi/20230817\\_mpsc-opo-performance-monitoring-enhancement-wg\\_meeting-summary.pdf](https://optn.transplant.hrsa.gov/media/4hmp40fi/20230817_mpsc-opo-performance-monitoring-enhancement-wg_meeting-summary.pdf).

**Table 4: Individual Allocation Deviations Reviewed by MPSC**

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
April 2024 Meeting	695

\*The MPSC changed its review processes during the COVID pandemic and numbers associated with reviews during that time are excluded.

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.

This Subcommittee was charged with analyzing the 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 anticipates that it may need to discuss increased data collection for allocation activities to ensure 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 its 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.

In late 2023, the Committee evaluated 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 considered 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. The Committee has requested the assistance of the Organ Procurement Organization (OPO) Committee to determine appropriate organ-specific late decline definitions through a referral on January 19, 2024.

At its January 2024 meeting, the Committee assessed data to enhance allocation monitoring efforts. After deliberation, the Committee opted to closely monitor allocations of exceptional concern, along with conducting random samplings of OPOs allocations out of sequence. This comprehensive monitoring plan garnered full approval from the MPSC on January 19th. While currently inactive, the Subcommittee stands ready to reconvene as required, responding to external allocation initiatives.

## Membership Requirements Revision

The Committee has resumed work on the Membership Requirements Revision project. The Committee is conducting a comprehensive review of all of the OPTN membership requirement bylaws in multiple phases. The Committee embarked on this comprehensive review to address revisions needed to implement an OPTN contract requirement for a process of periodic reassessment of members' membership status, ensure the provisions of the bylaws are in compliance with the OPTN Final Rule, address inconsistencies in the bylaws, and simplify the OPTN membership requirements.

Work on this multi-phase project began in 2019. Phase one of the project focuses on the application review process and general membership and designated transplant program requirements contained in *Appendix A Membership Application and Review*, *Appendix B Membership Requirements for Organ Procurement Organizations (OPOs)*, *Appendix C Membership Requirements for Histocompatibility Laboratories*, and *Appendix D Membership Requirements for Transplant Hospitals and Transplant Programs* of the OPTN Bylaws. The Committee approved a phase one proposal for Winter 2021 public comment that was put on hold to accommodate HRSA review. HRSA notified the Committee in Fall 2023 that work on this project could resume.

Since February 2024, the Committee has reviewed the 2021 proposal and discussed potential revisions to the proposal. In addition to minor revisions for consistency and clarity, the Committee discussed revisions to reduce the vagueness of the language describing when a transplant program needs to notify patients and the OPTN of changes to the program coverage plan and considered if additional revisions need to be made to address transplant professional misconduct. In addition, the Committee, with advice from the OPTN Vascularized Composite Allograft Transplantation Committee, has incorporated the uterus transplant program key personnel primary obstetrician-gynecologist into the key personnel and program coverage plan provisions in *Appendix D Membership Requirements for Transplant Hospitals and*



*Transplant Programs*. The Committee plans to release a proposal addressing revisions to *Appendix A Membership Application and Review*, *Appendix B Membership Requirements for Organ Procurement Organizations (OPOs)*, and *Appendix D Membership Requirements for Transplant Hospitals and Transplant Programs* for public comment this summer. Simultaneously, the Histocompatibility Committee is sponsoring a proposal that includes revisions to *Appendix C Membership Requirements for Histocompatibility Laboratories* that will be released for public comment this summer as well.

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

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 or African American 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 or African American 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. OPTN Contractor staff actively supported OPTN members with education and additional resources including a collaborative webinar which features effective practices.<sup>8</sup>

OPTN Contractor staff proactively reached out to primary kidney program administrators in the summer of 2023 to establish a dialogue about their level of awareness and compliance with the eGFR policy requirements. Throughout these conversations, OPTN Contractor 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*).

Effective January 2024, routine site surveys include interviews with transplant hospital staff regarding eGFR policy requirements. The objective is to ensure transplant hospital 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.

In January 2024, the MPSC reviewed the requirements for kidney programs regarding the review of their waitlists, notification to patients, submission of waiting time modifications, and attestation to the OPTN that the steps have been completed. As of January 4, 2024, one day after the deadline, all kidney programs had submitted their attestations. However, HRSA raised concerns over programs that have submitted an attestation and did not submit any or only submitted a few waiting time modifications while having Black or African American candidates on their waiting lists. Due to the concerns raised, the OPTN Executive Committee discussed potential further action or inquiry for these members to understand their process and try to ensure candidates are not continuing to be disadvantaged due to a

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<sup>8</sup> Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations, Notice of OPTN Policy and Bylaw Changes, OPTN, [https://optn.transplant.hrsa.gov/media/eempkchs/policy-notice\\_egfrwmods\\_mac\\_ki.pdf](https://optn.transplant.hrsa.gov/media/eempkchs/policy-notice_egfrwmods_mac_ki.pdf).

race inclusive eGFR calculation. As a next step, the MPSC was tasked with identifying a plan and threshold for further inquiry with kidney programs that may raise these concerns.

The MPSC determined that they needed to understand the trends in how many modifications were submitted for different programs and use that to identify who to further inquire with rather than reaching out to all programs. On January 29, 2024, the MPSC reviewed the number of potentially impacted candidates and how many modifications were submitted to determine which kidney programs would receive inquiries. The MPSC also met in closed session to discuss one member who did not meet the deadline for submitting its attestation. The MPSC considered potential options for how to obtain relevant information from identified programs, some of the challenges associated with the current policy, and a meaningful threshold for when to inquire. Eventually, they determined that they would look at the bottom 25th percentile, which would include any programs with 20 percent or less modifications. The Committee then determined that the letters should include an explanation for why the MPSC is contacting programs in the interest of patients; a request for the template notification letters with dates letters were sent; a description of the process for evaluating whether patients were eligible and submitting waiting time modifications, including how the evaluated patients who are referred on dialysis; and a description of the time and effort required for this policy implementation. The letters requested a response within 30 days, and the MPSC reviewed the cases at its March 29, 2024, meeting.

After the 30-day deadline, 56 members submitted responses to the MPSC inquiry. The MPSC reviewed the responses, requested additional information from 11 programs, and closed 45 with no action. The programs needing additional information may not have described their process for reviewing candidates on dialysis or already listed with a race-neutral eGFR to the MPSC's satisfaction. The MPSC will review additional information on those 11 programs at an upcoming meeting.

## Require Reporting of Patient Safety Events Project

The OPTN Board of Directors approved the Require Reporting of Patient Safety Events proposal at its December 2023 meeting. The purpose of this project was 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. The proposal was implemented on January 10, 2024.

## OPTN Contractor Process for HRSA/Executive Committee Notifiable Events

At the direction of the OPTN President, the OPTN Contractor will implement a process to increase OPTN leadership awareness of events that may pose a significant risk to patient health and public safety, consistent with existing requirements for contractor notification of HRSA Reportable Events.

## 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 (POC), 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 to date are outlined below:

**The MPSC referred six new projects following the February 16-17, 2023 meeting:**

*Standardize Reporting Information to Patient Safety Contacts*

In July 2023, 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 proposal went out for Winter 2024 public comment and is pending approval by the OPTN Board of Directors during the June 2024 meeting.

*Clarify Requirements for Reporting Post-Transplant Diseases*

This project began in early 2024 and has been split into two phases. Phase one is tentatively slated for Winter 2025 public comment and will include updating and clarifying policy language on expected versus unexpected disease transmissions, particularly regarding lungs since they are non-sterile. Phase two is targeted for Summer 2025 public comment and includes system enhancements focusing on improving 45-day follow up processes.

*Review Prohibited Vessel Storage Policies*

This referral was sent to the DTAC in response to requests from the community to modify vessel storage policies to better align with the advancements in treatment options for recipients who are HCV-positive. The DTAC and the Operations and Safety Committee (OSC) are supportive of modifying OPTN Policy 16.6.B *Extra Vessels Storage* to permit the storage of the presently prohibited 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 modify prohibited vessel storage policies.

*Create a Centralized Vessel Storage Reporting Mechanism*

In order to better understand the needs of the community, the OSC proposed developing a concept paper, or request for feedback, to engage the community and inform which policy changes needed to occur. The OSC obtained project approval from the Policy Oversight Committee in February 2024, but unfortunately, the Executive Committee did not approve this project to move forward in its current state. The OSC has prioritized other work and is not presently considering an alternative project plan to address this referral.

*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. This proposal was out for public comment in the Winter 2024 cycle and is on track to proceed to the OPTN Board of Directors in June 2024.

**The MPSC referred one new project following the July 25-27, 2023, meeting:**

### *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. The MPSC referred the inclusion of a checkbox to standardize how blood typing information is communicated between OPOs and transplant programs. The OSC agreed that this information would be valuable to collect and reduce the potential for information to be missed in the free text and maintain patient safety. The OSC is considering opportunities to include this data element into existing data collection proposal, as opposed to proceeding to public comment to add one new data element.

**The MPSC referred two new projects following the November 1-3, 2023, meeting:**

### *Transportation Events*

During the Summer 2023 public comment cycle, the MPSC's proposal '*Required Reporting of Patient Safety Events*' received feedback that led to the MPSC modifying the proposal post-public comment. The MPSC elected to remove the requirement to report when, "an organ did not arrive when expected and resulted in the intended candidate not receiving a transplant from the intended donor because of the transportation issue" and jointly refer this to the Operations and Safety Committee (OSC) and Data Advisory Committee (DAC). Through individual and joint discussions, the OSC decided they would prioritize this project and the DAC would provide ancillary support through their standard data involvement process. In order to better understand the types of transportation issues the community is experiencing, the OSC is hoping to obtain ancillary qualitative information from the "Late Declines Discovery Project" sponsored by the OPTN Expeditious Taskforce. This qualitative data will be analyzed and used to inform the OSC's next steps in determining how to incorporate standard transportation data collection.

### *Procurement Team Responsibilities*

*The goal of this referral was to clarify the responsibilities of all parties participating in organ recovery. While it remains the responsibility of the host OPO to ensure organ procurement quality per OPTN Policy 2.14.C Organ Procurement Procedures, it is increasingly common for transplant program procurement teams to be present in the operating room (OR) for organ recovery. These teams are not under the direct purview of the OPO which can complicate the ability of the OPO to provide oversight of organ procurement, particularly regarding the verification of medications, flush solution, and ex vivo perfusion devices that are brought into the recovery OR. The MPSC identified this as an opportunity for improvement whereby more explicit responsibilities outlined in policy for all parties involved in organ recovery, OPO and transplant hospital, would be helpful. This referral was sent to the OPO Committee*

*who agreed that this is an issue that needs to be addressed and they added it to their list of upcoming projects.*

## **The MPSC referred three new projects following the March 5-7, 2024 meeting:**

### *Late Declines*

This referral arose out of the recent work of the MPSC Allocations Review Subcommittee in reviewing allocations out of sequence (AOOS) and is a request for the OPO Committee to review potential data collection efforts around late declines to improve understanding of the problem and determine opportunities for better organ utilization. Generally, a late decline is the decline of an organ offer acceptance at a point in the procurement process such that following efforts to re-allocate and utilize the organ are negatively affected. Late declines can have a significant impact on both cold ischemic time (CIT) and organ discard rates and represent a significant shortcoming in our allocation system that needs to be addressed. Several members of the OPO Committee are participating in a “Late Declines Discovery Project” sponsored by the OPTN Expeditious Task Force. The OPO Committee anticipates receiving data on the first phase of the project in June 2024 and will utilize it to inform their next steps in addressing the issue.

### *eGFR Monitoring*

This referral arose out of a recommendation made by an MPSC member during the January 19th, 2024, committee meeting while discussing parameters for inquiries being sent about the eGFR attestations at the request of the OPTN Board of Directors. Policies 1.2 *Glomerular Filtration Rate (GFR)* and 3.7.D *Waiting Time modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations* currently outline the requirements for transplant programs to use race-neutral eGFR calculators and the requirements for waiting time modifications for kidney candidates affected by race-inclusive eGFR calculations, respectively. Neither policy outlines how transplant programs should ensure compliance and documentation, which leaves challenges when the MPSC needs to further audit these programs. To support consistency in practice and monitoring, OPTN Policy needs to specify the requirements that transplant programs must meet so the MPSC can monitor compliance. The MPSC has identified this gap in policy as an opportunity for improvement whereby more explicit direction for transplant programs would enable compliance monitoring to ensure that all candidates are being properly evaluated for eligibility for a waiting time modification. This referral was sent jointly to the Kidney and Minority Affairs Committees, and the Minority Affairs Committee is taking on the project with subject matter expertise from several Kidney Committee members.

### *Organ Chain of Custody*

The goal of this referral is to establish chain of custody requirements for all OPTN members involved in organ and vessel transportations to prevent issues including increased cold ischemic time, organ decline, and delayed cross matching. Currently, OPTN Policy 5.7 *Organ Check-In* requires transplant hospitals to have an organ check in procedure for any organ that is recovered outside of the hospital. This includes the optional use of the OPTN Organ Labeling, Packaging and Tracking System to facilitate the organ check in, however that is not widely utilized. There are no other affirmative hand off procedures required of OPTN members, such as an organ check out process. There have been an increasing number of submissions to the OPTN Patient Safety Reporting Portal (PSP) where chain of custody procedures on both sides of organ and vessel transportation might have prevented these issues. This referral was sent to the OSC and is still under consideration.

# 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.<sup>9</sup> This page includes reports to the OPTN Board of Directors, community messages from the MPSC Chair, patient safety resources, 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.<sup>10</sup> Since then, the MPSC has shared five messages to the community:

- Donation after circulatory death (DCD) protocols and managing multiple organs (December 2022)<sup>11</sup>
- Reducing risk and ensuring patient safety (July 2023)<sup>12</sup>
- Implementation of the Offer Acceptance performance metric and other recommendations (October 2023)<sup>13</sup>
- Upcoming eGFR waiting time modifications deadline and other updates (December 2023)<sup>14</sup>
- Reporting Patient Safety events, DCD organ recovery pre-OR huddles, and other recommendations (April 2024)<sup>15</sup>

At the conclusion of each in person meeting, the MPSC will determine what key takeaways from the meeting are essential to share with the community to improve practices and maintain patient safety.

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 directly with the community.

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.<sup>16</sup> This page and its documents are updated annually with the next update occurring in August 2024.

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<sup>9</sup> MPSC Resources, OPTN, <https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/mpsc-resources/>.

<sup>10</sup> Executive Committee Meeting Summary, December 4, 2022, OPTN, [https://optn.transplant.hrsa.gov/media/emgbm4a0/20221204\\_excom\\_meeting-summary.pdf](https://optn.transplant.hrsa.gov/media/emgbm4a0/20221204_excom_meeting-summary.pdf).

<sup>11</sup> MPSC Chair Communication, December 2022, OPTN, <https://optn.transplant.hrsa.gov/news/an-important-message-from-the-mpsc-on-donation-after-circulatory-death-dcd-protocols-and-managing-multiple-organs/>.

<sup>12</sup> MPSC Chair Communication, July 2023, OPTN, <https://optn.transplant.hrsa.gov/news/an-important-message-from-the-mpsc-on-reducing-risk-and-ensuring-patient-safety/>.

<sup>13</sup> MPSC Chair Communication, October 2023, OPTN, <https://optn.transplant.hrsa.gov/news/an-important-message-from-the-mpsc-on-the-implementation-of-the-offer-acceptance-performance-metric-and-other-recommendations/>.

<sup>14</sup> MPSC Chair Communication, December 2023, OPTN, <https://optn.transplant.hrsa.gov/news/an-important-message-from-the-mpsc-on-the-upcoming-egfr-waiting-time-modifications-deadline-and-other-updates/>.

<sup>15</sup> MPSC Chair Communication, April 2024, OPTN, <https://optn.transplant.hrsa.gov/news/an-important-message-from-the-mpsc-on-reporting-patient-safety-events-dcd-organ-recovery-pre-or-huddles-and-other-recommendations/>.

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



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 and its members. In its December 2022 report to the OPTN Board of 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.<sup>17</sup>

The MPSC resource page also notes the regional meeting updates that the MPSC has prioritized through recent years. As an additional touchpoint and opportunity to engage with the community at large, the MPSC Regional Representatives present to their respective regions twice a year. These updates allow the opportunity for the community to stay informed on what the MPSC has been working on and provide members with a forum to engage with their representatives and peers.

The MPSC continues to prioritize increasing transparency whenever possible. Over the last few MPSC meetings, the discussion has expanded to consider what types of requests members are hearing from the community. Some recommendations have included sharing patient safety process mapping, sharing required reported events and outcomes related to living donors, and sharing some of the orientation materials or doing a webinar where MPSC members share their experiences on the MPSC.

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.

## Engagement

As mentioned in the *Increasing Public Disclosure* section above, the MPSC Resources page on the OPTN website provides details and links to information regarding the Committee and current projects, Board reports, community messages, and patient safety and monitoring resources. Metrics regarding community engagement with these resources are listed below:

### Metrics Key

#### Website

- Page views: when a user views the page
- Events: when a user takes an action on the page (i.e., clicks a link)

#### Email

- Unique opens: when an individual user opens an email
- Clicks: number of times a link was clicked in the email

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<sup>17</sup> MPSC Report to the Board, December 2022, OPTN, [https://optn.transplant.hrsa.gov/media/ojenbrcm/20221205\\_mpsc\\_report-to-the-board.pdf](https://optn.transplant.hrsa.gov/media/ojenbrcm/20221205_mpsc_report-to-the-board.pdf)



## MPSC Resources Page

Access Dates	Page Views	Events
3/1/2023 - 4/30/2024	1,366	3,924

## Community Messages

Message	Email Date	Sent To	Open Rate	Clicks	Publish Date	Page Views	Events
1	12/7/2022	7802	43%	49	1/25/2023	109	279
2	7/7/2023	7529	46%	316	7/7/2023	156	389
3	10/6/2023	7713	37%	505	10/6/2023	221	582
4	12/8/2023	7711	43%	781	12/8/2023	93	288
5	4/15/2024	8518	29%	393	4/15/2024	201	585

Data through 4/30/2024

## 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.

Two resource documents have been created from the data on serious safety events reviewed by the Patient Safety workgroup and added to the MPSC Resources page on the OPTN website.<sup>18,19</sup> These resources provide information on avoiding ABO determination failures and avoiding pre-transplant verification failures. The MPSC will continue to review case trends to add to these patient safety resources.

## 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 OPTN Contractor staff collaborate on following the in-person meeting conclusion.

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

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<sup>18</sup> Avoiding ABO determination failures, January 2024, OPTN, [https://optn.transplant.hrsa.gov/media/3ancpq1/avoiding\\_abo\\_determination\\_failures.pdf](https://optn.transplant.hrsa.gov/media/3ancpq1/avoiding_abo_determination_failures.pdf)

<sup>19</sup> Avoiding pre-transplant verification failures, January 2024, OPTN, [https://optn.transplant.hrsa.gov/media/lkthgrzk/avoiding\\_pre-transplant\\_verification\\_failures.pdf](https://optn.transplant.hrsa.gov/media/lkthgrzk/avoiding_pre-transplant_verification_failures.pdf)

## Monitoring Activities

The charts below detail the various types and outcomes of MPSC monitoring activities between December 2023 and May 2024. 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.

## MPSC Operational Rules

The MPSC uses operational rules to manage the Committee's workload and provide guidance to OPTN Contractor staff on how to process certain issues consistently. For example, rather than asking all Committee members to review every case, the MPSC determined that OPTN Contractor 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 OPTN Contractor 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 re-approve 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.

As mentioned in the *Allocations Subcommittee* section above, the MPSC approved a new operational rule for monitoring allocations out of sequence during its January 19, 2024 meeting. This rule allows for the review of allocations of concern, as well as a random sample of 50%. During their meeting on April 23, 2024, the MPSC approved a new operational rule to address the use of protocols as part of the Expedited Placement Variance. This rule excludes matches from regular allocation out of sequence review and inquiry processes if the match was reported as using a variance protocol by a participating member and the appropriate protocol specific bypass codes were used.

## 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. The offer acceptance rate ratio metric was implemented in July 2023, and the pre-transplant waitlist mortality rate ratio metric will be implemented in July 2024.

In July 2023, 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. OPTN Contractor 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. OPTN Contractor 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, OPTN Contractor 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 December 2023 – May 2024; 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.

**Table 5: Number of Transplant Program Performance Submissions Reviewed**

MPSC Action	Program Type					Total
	Heart	Kidney	Liver	Lung	Pancreas	
Send initial inquiry	1	4	7	0	1	13
Continue to monitor	8	6	2	5	1	22
Skip a cycle	0	0	0	0	0	0
Informal discussions (held)	1	1	0	0	0	2
Informal discussions (offer pending)	0	0	0	0	0	0
Peer visit	0	0	0	0	0	0
Request to inactivate	0	0	0	0	0	0
Released	5	1	4	1	0	11

### *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:

**Table 6: Transplant Program Functional Inactivity Requirements**

Program Type	Inactive Period
Kidney, Liver or Heart	3 consecutive months
Lung	6 consecutive months
Pancreas (K/P)	Both of the following: <ol style="list-style-type: none"> <li>1. Failure to perform at least 2 transplants in 12 consecutive months</li> <li>2. Either of the following in 12 consecutive months: <ol style="list-style-type: none"> <li>a. A median waiting time of the program's K/P and pancreas candidates that is above the 67<sup>th</sup> percentile of the national waiting time</li> <li>b. The program had no K/P or pancreas candidates registered at the program</li> </ol> </li> </ol>
Stand-alone pediatric transplant programs	12 consecutive months

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, OPTN Contractor staff plan to propose revisions to the tools used in inactivity review.

**Table 7: Number of Transplant Program Functional Inactivity Submissions Reviewed**

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

### *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.

The MPSC's review cycle coincides with each of the MPSC's three in-person meetings each year. The MPSC did not have any OPOs under review for organ yield between December 2023 and May 2024.

## 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. There has been a recent short-term increase in informal discussions and peer visits, as the MPSC is hoping to intervene and help programs before issues become severe.

**Table 8: Compliance Reviews and MPSC Actions**

MPSC Action		Allocation Reviews	Site Surveys	Investigations
Action	Close with no action	15	9	15
	Follow up survey	n/a	4	n/a
	Notice of Noncompliance	4	0	12
	Letter of Warning	0	0	1
	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	0
	Interviews (held)	0	0	0
	Interviews (offer pending)	0	0	0
	Peer Visit	0	0	6

### *Allocation Reviews*

OPTN Contractor 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.

The table above notes 19 total allocation reviews for the year, which covers annual review for approximately two-thirds of OPOs as well as four transplant hospitals. 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 March and April 2024, the MPSC issued four Notices of Noncompliance to hospitals that accepted an organ for one candidate but transplanted a different candidate without consulting the host OPO. In April 2024, the MPSC conducted a review of 15 OPOs AOOS instances along with corresponding member responses, leading to no notices of non-compliance issued. Since February 2020, there have been a total of 18 Notices of Noncompliance for AOOS situations given to OPOs and 14 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.

### *Site Surveys*

OPTN Contractor staff survey each transplant program and OPO. If OPTN Contractor 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 six months after the survey. 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, OPTN Contractor 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 8 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 support the members, the Site Survey team is now also conducting continuous monitoring based on specific triggers and OPTN Waiting List management opportunities; examples of these efforts include monitoring the system for extra vessels that are not permissible by policy to be stored, lower respiratory COVID testing on lung donors, and multiple listed candidates who are transplanted at one hospital but not yet removed from another.

## *Investigations*

OPTN Contractor 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 OPTN Contractor staff, including Patient Services, Help Desk, and Policy and Community Relations.

OPTN Contractor staff investigate and 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, OPTN Contractor staff escalate reports of certain events to MPSC leadership and HRSA as required by the “HRSA Criteria” and the OPTN contract. OPTN Contractor 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. OPTN Contractor 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, OPTN Contractor 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, OPTN Contractor staff have historically closed the case and have not forwarded it to the MPSC for review.

OPTN Contractor staff continue to supply monthly reports of investigative activity to the MPSC at every meeting. This report is also meant to inform the Committee about events investigated that did not get referred for MPSC review. Examples of reasons why OPTN Contractor 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 OPTN Contractor 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 9 below summarizes the different types of applications reviewed from December 2023 through May 2024. A total of 321 applications were reviewed, showing a slight decrease from the 384 reviewed from December 2022 to May 2023. This decrease is attributed to a decline in the number of histocompatibility laboratory key personnel applications, which fell from 50 to 13 so far this year.

**Table 9: Number and Type of MPSC Application Reviews**

Type of Application	Number
<b>Transplant Hospitals and Programs</b>	
New Transplant Hospitals	1
New Programs and Components	21
Key Personnel Applications	205
Program and Component Conditional Approvals	4
Conditional to Full Approvals	2
Conditional Extensions	4
Program and Component Long Term Inactivations	20
Inactivation Extensions	1
Program and Component Reactivations	9
Program and Component Withdrawals	13
Transplant Hospital Withdrawals	1
<b>Organ Procurement Organizations (OPOs)</b>	
OPO Key Personnel Change Notifications	6
<b>Histocompatibility Labs</b>	
New Histocompatibility Lab	1
Histocompatibility Lab Key Personnel Changes	13
Histocompatibility Lab Withdrawals	2
<b>Non-Institutional Members</b>	
New Non-Institutional Members	3
Non-Institutional Membership Renewals	15
<b>TOTAL</b>	<b>321</b>

Data through 5/24/2024

## Additional OPTN Contactor 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 OPTN Contractor staff completed several pilot projects with input from the MPSC, broader deployment of IMFI started on October 1, 2022. During December 2023 – May 2024, two new IMFI engagements were initiated, six IMFI engagements were completed, and three projects are still ongoing as of May 1, 2024. The OPTN members who have engaged in an improvement project with IMFI during this time period have all been transplant programs and they have represented kidney, liver, lung, and heart programs. All IMFI activities continue to be conducted virtually, which has increased access and ability to run multiple projects at one time.



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

- OPTN Computer System Data Services Portal Training: OPTN Contractor 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: OPTN Contractor 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: OPTN Contractor 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 continues to be offered as performance improvement support to those members who receive a letter indicating that their program falls within the established operational boundary for performance improvement (or "yellow") zone for the new post-transplant performance monitoring metrics. One of the active projects as of May 2024, were started following the member receiving the letter letting them know that their program is in the "yellow zone".

OPTN Contractor staff continue outreach at regional meetings and community conferences. IMFI was included in the MPSC and Member Quality update at all OPTN Regional Meetings during the most recent meeting cycle and the IMFI team has been invited to present a plenary session at the upcoming Transplant Quality Institute in October 2024.

OPTN Contractor 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.

### *OPTN Offer Acceptance Collaborative*

The Collaborative Improvement team recently concluded the 6-month DCD Offer Acceptance Collaborative, which engaged 83 transplant programs (49 kidney, 12 liver, 17 heart, 5 lung) to address the variation in offer acceptance and improve offer acceptance rates at both the individual program and community levels. Participants worked on improvement projects across four key areas: revising and defining acceptance criteria, optimizing the response to organ offers, performing retrospective reviews, and strengthening waitlist management processes. The overall aim of the project was to increase offer acceptance rates during the active engagement period (February 2023 – July 2023) compared to the six months prior (August 2022 – January 2023). Organ-specific cohort aims and actual percent changes for the cohort compared to the rest of the nation are shown below. Additionally, a greater percentage of collaborative participants across all organ groups experienced improvement in offer acceptance ratios compared to programs in the rest of the nation.

Organ	OA Rate Aim	Cohort % Change	Rest of Nation % Change
Kidney	20% increase	21% increase	3% increase
Liver	15% increase	46% increase	9% decrease
Heart	15% increase	43% increase	16% increase
Lung	15% increase	11% decrease	23% decrease

The Offer Acceptance Collaborative Improvement Guide and Executive Report are posted on the OPTN website, with additional resources available on the *OPTN Offer Acceptance Collaborative playlist* in the OPTN Learning Management System (known as UNOSConnect<sup>SM</sup>).

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.

## Appendix A: Posters and Presentations

Title	Presenter(s)	Type of Presentation	Conference/ Meeting	Description
OPTN Membership and Professional Standards Committee (MPSC) and Member Quality Update	<b>MPSC Regional Representatives</b>	<b>Presentation</b>	<b>Winter 2024 Regional Meetings</b>	Update at all eleven Winter 2024 Regional Meetings about the new MPSC Chair Community emails, implementation of the upcoming pre-transplant mortality performance metric, and updates on other monitoring activities, among other topics.
Fostering Continuous Improvement: Building Upon Complementary Collaborative Improvement Initiatives	<b>Beth Overacre, Kate Breitbeil, and Heather Neil</b>	<b>Poster</b>	<b>Institute for Healthcare Improvement (IHI)</b>	This poster outlined the framework and results of the OPTN DCD Procurement and Lung Collaboratives, highlighting how bringing transplant professionals together with a desire to improve in the same areas can drive change and progress.
Improving System Efficiencies in Organ Offer Acceptance Through a Collaborative Engagement	<b>Beth Overacre, Whitney Bailey, and Molly Maxwell</b>	<b>Presentation</b>	<b>NATCO Annual Meeting</b>	This presentation highlighted the framework and results of the OPTN Offer Acceptance Collaborative. Representatives from two participating programs also shared their improvement journeys.

## Appendix B: Monitoring Effectiveness Baseline Report

**OPTN** ORGAN PROCUREMENT AND  
TRANSPLANTATION NETWORK

Contract: HSH250-2019-00001C  
Task: United Network for Organ Sharing  
Item: A140  
Due: 10 business days prior to each MPSC multi day meeting  
Submitted: February 20, 2024

# Monitoring Effectiveness Baseline Report

# MONITORING EFFECTIVENESS BASELINE REPORT

PWS Excerpt:

3BUnited Network for Organ Sharing	<p><i>The Contractor shall measure effectiveness of the processes used to identify compliance, encourage improvement, and determine sanctions</i></p> <p>The Contractor shall develop objective metrics to monitor effectiveness of Contractor processes used to monitor OPTN members, identify compliance problems, encourage performance 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.</p> <p><u>Performance Standards</u></p> <p>a) Standard: Findings that warrant review of existing processes or development of new processes lead to proposals to change processes.</p>
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**Table 1. Quantity of deceased donor organ allocations resulting in a transplant wherein a deviation of allocation policy occurred, by type of organ, type of deviation and fiscal quarter during which the deviation took place,  
October 1<sup>st</sup>, 2021 - September 30<sup>th</sup>, 2023**

Organ Type	Fiscal Quarter	Total	Allocation Out of Sequence	Directed Donations	Other	Clean
All Combined	FY2022 Q1	8515	519 (6.1%)	38 (0.45%)	4 (0.05%)	7954 (93.41%)
	FY2022 Q2	8787	708 (8.06%)	58 (0.66%)	2 (0.02%)	8019 (91.26%)
	FY2022 Q3	9192	788 (8.57%)	78 (0.85%)	13 (0.14%)	8313 (90.44%)
	FY2022 Q4	9721	876 (9.01%)	56 (0.58%)	12 (0.12%)	8777 (90.29%)
	FY2023 Q1	9676	938 (9.69%)	57 (0.59%)	5 (0.05%)	8676 (89.67%)
	FY2023 Q2	9678	1209 (12.49%)	56 (0.58%)	6 (0.06%)	8407 (86.87%)
	FY2023 Q3	10580	1564 (14.78%)	79 (0.75%)	12 (0.11%)	8925 (84.36%)
	FY2023 Q4	10249	1487 (14.51%)	82 (0.8%)	12 (0.12%)	8668 (84.57%)
Total over all quarters		76398	8089 (10.59%)	504 (0.66%)	66 (0.09%)	67739 (88.67%)
HR	FY2022 Q1	927	23 (2.48%)	0 (0%)	0 (0%)	904 (97.52%)
	FY2022 Q2	938	15 (1.6%)	2 (0.21%)	0 (0%)	921 (98.19%)
	FY2022 Q3	1022	21 (2.05%)	2 (0.2%)	0 (0%)	999 (97.75%)
	FY2022 Q4	1100	26 (2.36%)	0 (0%)	0 (0%)	1074 (97.64%)
	FY2023 Q1	1113	23 (2.07%)	0 (0%)	1 (0.09%)	1089 (97.84%)
	FY2023 Q2	1081	30 (2.78%)	0 (0%)	0 (0%)	1051 (97.22%)
	FY2023 Q3	1219	37 (3.04%)	0 (0%)	0 (0%)	1182 (96.96%)
	FY2023 Q4	1203	45 (3.74%)	2 (0.17%)	0 (0%)	1156 (96.09%)
Total over all quarters		8603	220 (2.56%)	6 (0.07%)	1 (0.01%)	8376 (97.36%)
IN	FY2022 Q1	27	0 (0%)	0 (0%)	0 (0%)	27 (100%)
	FY2022 Q2	16	1 (6.25%)	0 (0%)	0 (0%)	15 (93.75%)
	FY2022 Q3	22	2 (9.09%)	0 (0%)	0 (0%)	20 (90.91%)
	FY2022 Q4	22	3 (13.64%)	0 (0%)	0 (0%)	19 (86.36%)
	FY2023 Q1	22	0 (0%)	0 (0%)	0 (0%)	22 (100%)
	FY2023 Q2	17	0 (0%)	1 (5.88%)	0 (0%)	16 (94.12%)
	FY2023 Q3	29	1 (3.45%)	0 (0%)	0 (0%)	28 (96.55%)
	FY2023 Q4	23	0 (0%)	0 (0%)	0 (0%)	23 (100%)
Total over all quarters		178	7 (3.93%)	1 (0.56%)	0 (0%)	170 (95.51%)
KI	FY2022 Q1	4665	300 (6.43%)	31 (0.66%)	2 (0.04%)	4332 (92.86%)
	FY2022 Q2	4832	453 (9.38%)	48 (0.99%)	1 (0.02%)	4330 (89.61%)
	FY2022 Q3	5020	489 (9.74%)	66 (1.31%)	8 (0.16%)	4457 (88.78%)
	FY2022 Q4	5333	576 (10.8%)	51 (0.96%)	8 (0.15%)	4698 (88.09%)
	FY2023 Q1	5293	645 (12.19%)	46 (0.87%)	1 (0.02%)	4601 (86.93%)
	FY2023 Q2	5238	822 (15.69%)	46 (0.88%)	1 (0.02%)	4369 (83.41%)
	FY2023 Q3	5689	1008 (17.72%)	67 (1.18%)	0 (0%)	4614 (81.1%)
	FY2023 Q4	5518	993 (18%)	71 (1.29%)	0 (0%)	4454 (80.72%)
Total over all quarters		41588	5286 (12.71%)	426 (1.02%)	21 (0.05%)	35855 (86.21%)
LI	FY2022 Q1	2079	174 (8.37%)	7 (0.34%)	1 (0.05%)	1897 (91.25%)
	FY2022 Q2	2121	202 (9.52%)	6 (0.28%)	0 (0%)	1913 (90.19%)
	FY2022 Q3	2206	229 (10.38%)	10 (0.45%)	4 (0.18%)	1963 (88.98%)
	FY2022 Q4	2298	234 (10.18%)	4 (0.17%)	3 (0.13%)	2057 (89.51%)
	FY2023 Q1	2306	240 (10.41%)	8 (0.35%)	3 (0.13%)	2055 (89.12%)
	FY2023 Q2	2384	307 (12.88%)	7 (0.29%)	4 (0.17%)	2066 (86.66%)
	FY2023 Q3	2537	394 (15.53%)	10 (0.39%)	10 (0.39%)	2123 (83.68%)
	FY2023 Q4	2486	368 (14.8%)	9 (0.36%)	9 (0.36%)	2100 (84.47%)
Total over all quarters		18417	2148 (11.66%)	61 (0.33%)	34 (0.18%)	16174 (87.82%)
LU	FY2022 Q1	594	15 (2.53%)	0 (0%)	0 (0%)	579 (97.47%)
	FY2022 Q2	657	25 (3.81%)	1 (0.15%)	1 (0.15%)	630 (95.89%)
	FY2022 Q3	705	33 (4.68%)	0 (0%)	1 (0.14%)	671 (95.18%)
	FY2022 Q4	696	22 (3.16%)	0 (0%)	1 (0.14%)	673 (96.7%)
	FY2023 Q1	710	23 (3.24%)	2 (0.28%)	0 (0%)	685 (96.48%)
	FY2023 Q2	731	43 (5.88%)	0 (0%)	1 (0.14%)	687 (93.98%)
	FY2023 Q3	844	109 (12.91%)	0 (0%)	2 (0.24%)	733 (86.85%)
	FY2023 Q4	784	63 (8.04%)	0 (0%)	3 (0.38%)	718 (91.58%)
Total over all quarters		5721	333 (5.82%)	3 (0.05%)	9 (0.16%)	5376 (93.97%)
PA	FY2022 Q1	223	7 (3.14%)	0 (0%)	1 (0.45%)	215 (96.41%)
	FY2022 Q2	223	12 (5.38%)	1 (0.45%)	0 (0%)	210 (94.17%)

FY2022 Q3	217	14 (6.45%)	0 (0%)	0 (0%)	203 (93.55%)
FY2022 Q4	272	15 (5.51%)	1 (0.37%)	0 (0%)	256 (94.12%)
FY2023 Q1	232	7 (3.02%)	1 (0.43%)	0 (0%)	224 (96.55%)
FY2023 Q2	227	7 (3.08%)	2 (0.88%)	0 (0%)	218 (96.04%)
FY2023 Q3	262	15 (5.73%)	2 (0.76%)	0 (0%)	245 (93.51%)
FY2023 Q4	235	18 (7.66%)	0 (0%)	0 (0%)	217 (92.34%)
<i>Total over all quarters</i>	<i>1891</i>	<i>95 (5.02%)</i>	<i>7 (0.37%)</i>	<i>1 (0.05%)</i>	<i>1788 (94.55%)</i>

Table 1 shows the number of organ allocations resulting in a transplant that deviated from organ allocation policy between October 1st, 2021 and September 30th, 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 allocations where the recipient was not on the match run, local backups, 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) created a Subcommittee 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. Additional projects have also been created that incorporate allocation out of sequence analyses to inform MPSC decision-making.



**Table 2. Quantity of patient safety event cases processed by Compliance and Safety Investigators, subset by whether the case was referred to the MPSC  
April 1<sup>st</sup>, 2023 - September 30<sup>th</sup>, 2023**

Fiscal quarter	Total number of cases	Number of cases where investigators are still determining whether to refer to the MPSC	Number of cases where investigators determined whether to refer the MPSC, and whether the cases were referred	
			Referred	Not referred
FY2023 Q3	126	34 (26.98%)	27 (21.43%)	65 (51.59%)
FY2023 Q4	150	66 (44%)	17 (11.33%)	67 (44.67%)

Table 2 shows the number of patient safety event cases processed by Compliance and Safety Investigators (CSIs) between April 1<sup>st</sup>, 2023 and September 30<sup>th</sup>, 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.",**

**October 1st, 2021 and September 30th, 2023**

Fiscal quarter	Total number of responses	Respondent's answer	
		Agree or strongly agree	Disagree or strongly disagree
FY2022 Q1	17	16 (94.12%)	1 (5.88%)
FY2022 Q2	18	17 (94.44%)	1 (5.56%)
FY2022 Q3	17	16 (94.12%)	1 (5.88%)
FY2022 Q4	22	22 (100%)	0 (0%)
FY2023 Q1	19	19 (100%)	0 (0%)
FY2023 Q2	15	15 (100%)	0 (0%)
FY2023 Q3	16	15 (93.75%)	1 (6.25%)
FY2023 Q4	16	16 (100%)	0 (0%)
<i>Total over all quarters</i>	<i>140</i>	<i>136 (97.14%)</i>	<i>4 (2.94%)</i>

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 October 1st, 2021 and September 30th, 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.

**Table 4. Proportion of members with a compliance issue resulting in MPSC action that have another compliance issue resulting in MPSC action within 12 months  
October 1st, 2021 - September 30th, 2022**

Fiscal quarter	Total number of members with a compliance issue resulting in an MPSC action	Number of members with a compliance issue resulting in an MPSC action and another within 12 months	Number of 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
FY2022 Q1	22	8	14	36.36%
FY2022 Q2	29	11	18	37.93%
FY2022 Q3	3	3	0	100%
FY2022 Q4	31	11	20	35.48%

Table 4 shows the number of members between October 1st, 2021 and September 30th, 2022, 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. The data ends in FY2022 to allow a full 12-month period after the MPSC action. 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.

**Table 5. Transplant recipient program, living donor program, and organ procurement organization policy compliance rates, subset by policy and associated organ type, October 1st, 2021 - September 30th, 2023**

Member type	Organ	Policy	Type	Total number of items	Were items compliant?	
					Yes	No
Living Donor	LDK	13.4.A (LDK)	Records	105	94 (89.52%)	11 (10.48%)
		13.4.C	Elements	1728	1490 (86.23%)	238 (13.77%)
		14.4.B	Elements	5951	5922 (99.51%)	29 (0.49%)
		18.4.A (Accuracy) 1 Year	Elements	234	229 (97.86%)	5 (2.14%)
	LDL	14.4.C	Elements	870	855 (98.28%)	15 (1.72%)
	Non-specified	14.1.A	Elements	9269	9022 (97.34%)	247 (2.66%)
		14.2.A	Elements	2968	2809 (94.64%)	159 (5.36%)
		14.3	Elements	33323	32283 (96.88%)	1040 (3.12%)
		14.4.A	Elements	23131	22957 (99.25%)	174 (0.75%)
		14.7	Records	755	715 (94.7%)	40 (5.3%)
		14.8.B	Records	651	509 (78.19%)	142 (21.81%)
		18.1 (Accuracy)	Elements	14657	14240 (97.15%)	417 (2.85%)
		18.1 (Timely LDRs)	Forms	3708	3438 (92.72%)	270 (7.28%)
OPO		2.2 #14	Records	570	553 (97.02%)	17 (2.98%)
		2.2 #15	Records	600	598 (99.67%)	2 (0.33%)
		2.2 #2	Records	570	570 (100%)	0 (0%)
		2.2 #5	Records	570	570 (100%)	0 (0%)
		2.3	Records	560	560 (100%)	0 (0%)
		2.4	Records	570	570 (100%)	0 (0%)
		2.11.B #2c [LI]	Records	392	390 (99.49%)	2 (0.51%)
		2.11.E #5 & #6 [PA]	Records	46	46 (100%)	0 (0%)
		2.14.B	Records	570	555 (97.37%)	15 (2.63%)
		2.14.C #6	Records	575	563 (97.91%)	12 (2.09%)
		2.5	Records	570	567 (99.47%)	3 (0.53%)
		2.6.B	Records	155	153 (98.71%)	2 (1.29%)
		2.8 #7	Records	568	565 (99.47%)	3 (0.53%)
		2.9 #2	Records	570	570 (100%)	0 (0%)
		15.4.A	Records	570	560 (98.25%)	10 (1.75%)
		16.5	Records	570	566 (99.3%)	4 (0.7%)
		18.1 (Accuracy DDRs)	Elements	23700	23510 (99.2%)	190 (0.8%)
		18.1 (Non-Eligible)	Records	258	232 (89.92%)	26 (10.08%)
		18.1 (Timeliness PTRs)	Forms	59328	59121 (99.65%)	207 (0.35%)
		18.1 (Timeliness DDRs)	Forms	12765	12694 (99.44%)	71 (0.56%)
		18.1 (Timeliness Feedback)	Forms	13355	13310 (99.66%)	45 (0.34%)
		Accuracy of DonorNet	Elements	9800	9743 (99.42%)	57 (0.58%)
		Accuracy of Serologies	Records	585	580 (99.15%)	5 (0.85%)
Transplant Recipient	HR	6.1	Listings	1210	1193 (98.6%)	17 (1.4%)
		6.1/6.2/6.3/6.4 DEE	Listings	2229	2142 (96.1%)	87 (3.9%)
		6.2	Listings	405	405 (100%)	0 (0%)
		6.4	Listings	644	644 (100%)	0 (0%)
	KI	5.3.C	Records	664	624 (93.98%)	40 (6.02%)
		8.3	Listings	1392	1360 (97.7%)	32 (2.3%)
		8.3 DEE	Listings	1426	1394 (97.76%)	32 (2.24%)
		8.4.A	Records	1050	1033 (98.38%)	17 (1.62%)
		8.4.D	Records	103	100 (97.09%)	3 (2.91%)
		8.4.F	Records	341	316 (92.67%)	25 (7.33%)
		8.4.G	Records	103	103 (100%)	0 (0%)
		8.4.G DEE	Records	113	107 (94.69%)	6 (5.31%)
	LI	9.1.(A-E)/9.5 DEE	Listings	2230	2137 (95.83%)	93 (4.17%)
		9.1.A/9.1.B/9.1.C/9.2	Listings	364	356 (97.8%)	8 (2.2%)
		9.1.D	Listings	52	50 (96.15%)	2 (3.85%)
		9.2	Listings	32	32 (100%)	0 (0%)
		9.5	Listings	13	13 (100%)	0 (0%)
		9.5/9.2	Listings	1807	1780 (98.51%)	27 (1.49%)
		9.9	Records	255	252 (98.82%)	3 (1.18%)

	9.9 DEE	Records	252	234 (92.86%)	18 (7.14%)
	16.6.B Destroying	Vessels	10744	10700 (99.59%)	44 (0.41%)
	16.6.C Reporting	Vessels	10744	10110 (94.1%)	634 (5.9%)
LU	10.1	Listings	1339	1170 (87.38%)	169 (12.62%)
	10.1 DEE	Listings	1249	1207 (96.64%)	42 (3.36%)
	10.1.A/10.1.B/10.1.C (Peds)	Listings	35	32 (91.43%)	3 (8.57%)
PA	11.3.B	Records	528	517 (97.92%)	11 (2.08%)
	11.3.B DEE	Records	508	496 (97.64%)	12 (2.36%)
Non-specified	5.8.B	Records	5160	5001 (96.92%)	159 (3.08%)
	15.2	Records	4169	2978 (71.43%)	1191 (28.57%)
	15.2 (TRR Accuracy)	Records	20	18 (90%)	2 (10%)
	15.3.B	Records	1637	1548 (94.56%)	89 (5.44%)
	15.3.C	Records	3812	2894 (75.92%)	918 (24.08%)
	18.1 Accuracy (TRF 6 Mos)	Elements	4482	3534 (78.85%)	948 (21.15%)
	18.1 Timely (TRF 1 Year)	Forms	19555	15057 (77%)	4498 (23%)
	18.1 Timely (TRF 2 Years)	Forms	17913	13800 (77.04%)	4113 (22.96%)
	18.1 Timely (TRF 6 Mos)	Forms	20318	15874 (78.13%)	4444 (21.87%)
	18.1 Timely (TRR)	Forms	22432	18173 (81.01%)	4259 (18.99%)

Table 5 shows the quantity of the elements, records, listings, and vessels of transplant programs, living donor components of programs, and organ procurement organizations reviewed by site surveyors, by policy and whether the surveyor identified an item as being compliant with policy. This includes records that were surveyed between October 1st, 2021 – September 30th, 2023. **Highlighted are policies with a greater than 5 percent non-compliance rate.** Targeted education and monitoring changes and system enhancements have been made to 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 them.

#### 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 8.4.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. Note: Completion of the CPRA Approval Form is no longer required effective May 2, 2024, per OPTN Board of Directors approval in December 2023.

#### OPTN Policies 15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements and

#### 15.3.C: 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.

PaO2 values now allow a decimal point to allow for more accurate data entry.

**Table 6. Proportion of members which underwent a routine site survey, and based on those findings the MPSC or Member Quality either did or did not recommend that they participate in a focused desk review,  
October 1st, 2021 - September 30th, 2023**

Member type	Fiscal quarter	Total number of programs surveyed	Did the MPSC or UNOS recommend for a focused desk review?	
			No	Yes
Living Donor	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	17	10 (58.82%)	7 (41.18%)
	FY2023 Q4	17	11 (64.71%)	6 (35.29%)
<i>Total over all quarters</i>		<i>151</i>	<i>93 (61.59%)</i>	<i>58 (38.41%)</i>
OPO	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%)
	FY2023 Q4	5	5 (100%)	0 (0%)
<i>Total over all quarters</i>		<i>39</i>	<i>35 (89.74%)</i>	<i>4 (10.26%)</i>
Transplant Recipient	FY2022 Q1	46	25 (54.35%)	21 (45.65%)
	FY2022 Q2	57	28 (49.12%)	29 (50.88%)
	FY2022 Q3	69	27 (39.13%)	42 (60.87%)
	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	47	18 (38.3%)	29 (61.7%)
	FY2023 Q4	44	22 (50%)	22 (50%)
<i>Total over all quarters</i>		<i>462</i>	<i>213 (46.1%)</i>	<i>249 (53.9%)</i>

Table 6 indicates the number and proportion of transplant recipient routine site surveys which were performed between October 1st, 2021 and September 30th, 2023 and resulted in a recommendation from the MPSC or Member Quality 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.



**Table 7. Proportion of members which underwent a focused desk review, and based on those findings the MPSC or Member Quality either did or did not recommend that they participate in another focused desk review, October 1st, 2021 and September 30th, 2023**

Member type	Fiscal quarter	Total number of programs surveyed	Did the MPSC or UNOS recommend for an additional focused desk review?	
			No	Yes
Living Donor	FY2022 Q1	11	10 (90.91%)	1 (9.09%)
	FY2022 Q2	16	14 (87.5%)	2 (12.5%)
	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%)
	FY2023 Q4	8	8 (100%)	0 (0%)
	<i>Total over all quarters</i>	<i>59</i>	<i>51 (86.44%)</i>	<i>8 (13.56%)</i>
OPO	FY2022 Q1	0		
	FY2022 Q2	1	1 (100%)	0 (0%)
	FY2022 Q3	1	1 (100%)	0 (0%)
	FY2022 Q4	0		
	FY2023 Q1	0		
	FY2023 Q2	3	3 (100%)	0 (0%)
	FY2023 Q3	0		
	FY2023 Q4	0		
	<i>Total over all quarters</i>	<i>5</i>	<i>5 (100%)</i>	<i>0 (0%)</i>
Transplant Recipient	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	8 (100%)	0 (0%)
	FY2023 Q1	25	17 (68%)	8 (32%)
	FY2023 Q2	37	22 (59.46%)	15 (40.54%)
	FY2023 Q3	41	26 (63.41%)	15 (36.59%)
	FY2023 Q4	52	36 (69.23%)	16 (30.77%)
	<i>Total over all quarters</i>	<i>243</i>	<i>175 (72.02%)</i>	<i>68 (27.98%)</i>

Table 7 shows the proportion of focused desk reviews between October 1st, 2021 and September 30th, 2023 which resulted in either the MPSC or Member Quality 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.

**Table 8. Proportion of members participating in at least two routine site surveys between October 1st, 2018 and September 30<sup>th</sup>, 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 type	Organ type	Policy	Item type	No desk review recommendation cohort			Yes desk review recommendation cohort			Yes % Increase - No % Increase
				Decrease	Same	Increase	Decrease	Same	Increase	
Living Donor	LDK	13.4.A (LDK)	Records	1	7	0	0	4	1	
		13.4.C	Elements	3	3	2	1	0	4	
		14.4.B	Elements	4	30	3	3	21	3	
		18.4.A (Accuracy) 1 Year	Elements	0	1	1	0	0	0	
		<i>Total LDK</i>	*	8	41	6	4	25	8	22
	LDL	14.4.C	Elements	1	7	1	1	2	0	
	Non-specified	14.1.A	Elements	13	21	12	7	3	20	41
		14.2.A	Elements	0	43	3	6	10	14	40
		14.3	Elements	14	14	18	13	0	17	18
		14.4.A	Elements	11	26	9	9	9	12	20
		14.7	Records	1	40	4	5	11	14	38
		18.1 (Accuracy)	Elements	16	12	17	16	5	9	
		18.1 (Timely LDRs)	Forms	6	30	10	6	21	3	-12
		<i>Total LD non-specified</i>	*	62	193	74	63	61	89	42
OPO		15.4.A	Records	5	16	6	1	0	0	
		16.5	Records	3	20	4	0	1	0	
		18.1 (Non-Eligible)	Records	6	10	6	1	0	0	
		18.1 (Timeliness PTRs)	Forms	9	8	10	0	0	1	
		18.1 (Timeliness DDRs)	Forms	8	11	8	1	0	0	
		18.1 (Timeliness Feedback)	Forms	9	12	6	0	0	1	
		2.11.B #2c [LI]	Records	2	23	2	0	1	0	
		2.11.E #5 & #6 [PA]	Records	0	12	0	0	1	0	
		2.14.B	Records	3	23	1	0	0	1	
		2.14.C #6	Records	5	17	5	1	0	0	
		2.2 #14	Records	5	11	11	1	0	0	
		2.2 #15	Records	1	20	6	0	1	0	
		2.2 #2	Records	0	27	0	0	1	0	
		2.2 #5	Records	0	27	0	0	1	0	
		2.3	Records	0	27	0	0	1	0	
		2.4	Records	0	27	0	0	1	0	
		2.5	Records	2	23	2	0	1	0	
		2.6.B	Records	1	23	1	0	1	0	
		2.8 #7	Records	1	21	5	0	0	1	
		2.9 #2	Records	0	27	0	0	1	0	
		Accuracy of Serologies	Records	1	25	1	0	0	1	

		<i>Total OPO</i>	*	61	410	74	5	11	5	24
Transplant Recipient	HR	6.1	Listings	2	20	3	3	7	3	11
		6.1/6.2/6.3/6.4 DEE	Listings	8	13	9	9	2	4	
		6.2	Listings	0	14	3	0	4	0	
		6.4	Listings	0	26	0	0	13	0	
		<i>Total HR</i>	*	10	73	15	12	26	7	15
	KI	5.3.C	Records	2	20	1	3	24	5	11
		8.3	Listings	1	32	0	12	18	10	25
		8.3 DEE	Listings	2	30	1	7	29	4	
		8.4.A	Records	2	30	0	6	30	2	
		8.4.D	Records	0	3	0	1	9	0	
		8.4.F	Records	0	16	5	6	19	9	
		8.4.G	Records	0	5	0	0	6	0	
		8.4.G DEE	Records	0	5	0	0	5	0	
		<i>Total KI</i>	*	7	141	7	35	140	30	15
	LI	16.6.B Destroying	Vessels	5	14	3	4	17	3	
		16.6.C Reporting	Vessels	7	3	12	8	2	14	
		9.1.(A-E)/9.5 DEE	Listings	4	7	13	8	4	13	
		9.1.A/9.1.B/9.1.C/9.2	Listings	0	21	0	2	15	2	11
		9.5/9.2	Listings	3	20	0	6	13	5	21
		9.9	Records	0	12	0	0	21	1	
		9.9 DEE	Records	0	12	0	4	14	4	18
		<i>Total LI</i>	*	19	89	28	32	86	42	26
LU		10.1	Listings	2	0	2	1	0	0	
		10.1 DEE	Listings	1	0	3	0	0	1	
		<i>Total LU</i>	*	3	0	5	1	0	1	
PA		11.3.B	Records	0	0	0	0	0	3	
		11.3.B DEE	Records	0	0	0	0	1	2	
		<i>Total PA</i>		3	0	5	1	0	1	
Non-specified		5.8.B	Records	5	94	14	9	15	68	62
		15.3.B	Records	3	75	4	17	44	20	20
		<i>Total DD non-specified</i>	*	8	169	18	26	59	88	

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Table 8 shows the quantity of pairs of all routine member site surveys where the member had two routine site surveys between October 1st, 2018 and September 30th, 2023 where a specific policy was reviewed. It compares the compliance rate of the first (2<sup>nd</sup> 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.