

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

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The OPTN Membership and Professional Standards Committee (MPSC) is pleased to provide this report to the OPTN Board of Directors. This report reflects the MPSC's work from June 2024 – November 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:

- Implementation of the pre-transplant mortality rate ratio performance metric in July 2024
- Modifications to criteria for post-transplant graft survival metrics
- Revisions to membership 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
- Updates on monitoring activities and trends

Updates on Current Committee Projects

Transplant Program Performance Metrics Enhancements

In December 2021, the OPTN Board of Directors approved a proposal to enhance the transplant program performance monitoring system.¹ The new monitoring system involves four risk-adjusted measures related to the patient journey through the transplant process, pre-transplant mortality, offer acceptance, 90-day graft survival, and 1-year conditional on 90-day graft survival. The last of the four metrics, pre-transplant mortality, was implemented in July 2024 and the first inquiries were sent to transplant programs in August. In preparation for the implementation, a town hall webinar was held on June 28, 2024, that featured the MPSC Chair and Scientific Registry of Transplant Recipients (SRTR) staff. As part of the implementation of the pre-transplant mortality metric, the MPSC held a session in October to review sample submissions from members and address themes to encourage consistency in review and decision-making on these cases.

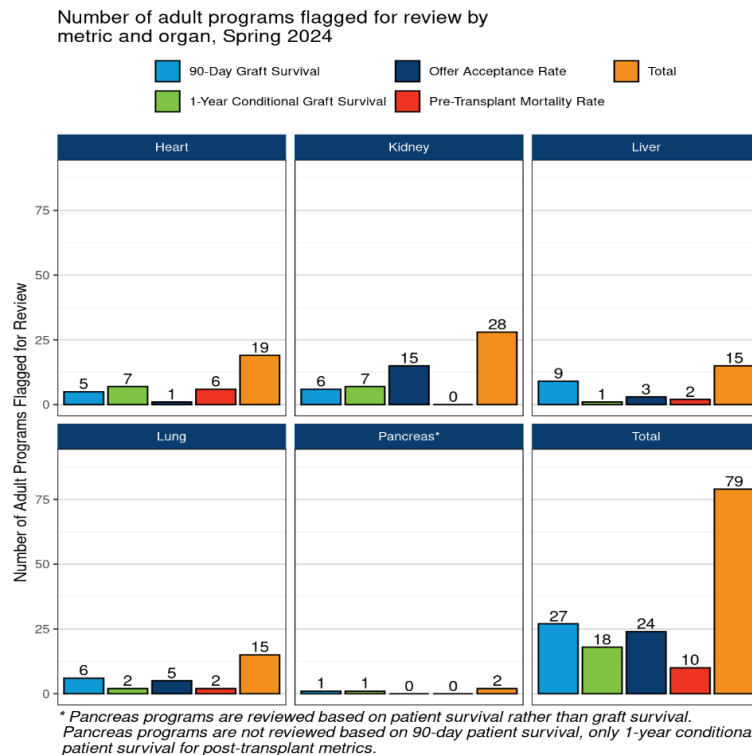
¹ Enhance Transplant Program Performance Monitoring System, Notice of OPTN Policy and Bylaw Changes, OPTN, https://optn.transplant.hrsa.gov/media/q0ud4hlp/policy-notice_tx-prgm-performance-monitoring_dec-2021.pdf.

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 MPSC reviewed the second annual post-implementation monitoring report at its November 2024 meeting. Committee members provided feedback for future reports including removing the COVID era from the predictive interval and considering observed to expected analysis to account for donor factors in the utilization rate data.

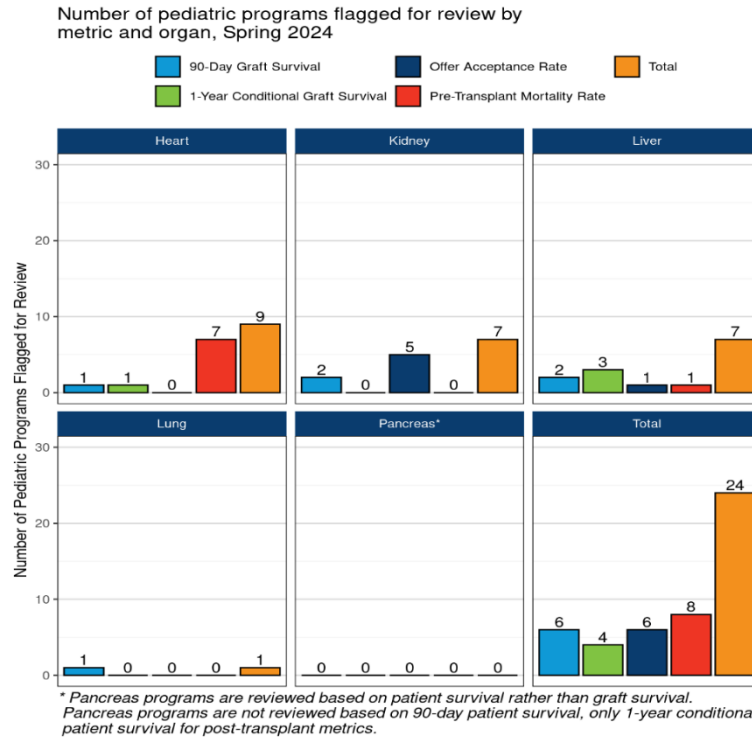
The MPSC continues to evaluate the number of programs identified for review and qualitative insights from individual program interactions. During the MPSC's July 2024 meeting, the Committee reviewed the data contained in **Figures 1 and 2** on the number of adult and pediatric flags under the recently implemented post-transplant outcomes, offer acceptance and pre-transplant mortality metrics.² The next round of new data will be available in March 2025.

Figure 1: Number of Adult Flags for New Performance Metrics in the July 2024 Program Specific Reports



² MPSC Meeting Summary, July 23-25, 2024, OPTN, https://optn.transplant.hrsa.gov/media/423fsumo/20240723_mpsc_meeting_summary_public.pdf.

Figure 2: Number of Pediatric Flags for New Performance Metrics in the July 2024 Program Specific Reports



Update Criteria for Post-Transplant Graft Survival Metrics

The Committee approved the release of a proposal to update the criteria for post-transplant graft survival metrics at its June 28, 2024, meeting. The proposal proposes a change to the flagging threshold for 90-day graft survival and the 1-year conditional on 90-day graft survival for adult transplant recipients from a 50% probability that the transplant program’s hazard ratio is greater than 1.75 (75% higher than expected) to a 50% probability that the transplant program’s hazard ratio is greater than 2.25 (125% higher than expected). For the post-transplant graft survival metrics, a 1.0 hazard ratio indicates a transplant program is performing as expected taking into account the donor and recipient characteristics and a higher hazard ratio indicates a program is performing worse than expected. The MPSC noted that a threshold of 2.25 hazard ratio would continue to identify the transplant programs that have the greatest need for improvement and that the majority of serious patient safety issues are identified through other monitoring activities. This change to the threshold should reduce transplant program concern about potential MPSC performance monitoring and encourage transplant programs to accept and transplant more complex donor organs resulting in more candidates receiving a transplant faster. The Committee decided to not change the thresholds for 90-day graft survival and the 1-year conditional on 90-day graft survival for pediatric transplant recipients based on a need to for closer monitoring of transplant outcomes for children based on public perception and a recognition that there are additional important considerations supporting avoidance of more complex donor organs for use in transplants in children, and therefore, changes to the metric thresholds should not be made to encourage use of these organs in pediatric recipients. The Committee considered making a change to the offer acceptance rate ratio flagging threshold but decided not to propose a change at this time as there has not been sufficient time to evaluate the effect of review of transplant programs for offer

acceptance since the metric's implementation in July 2023 and to provide an opportunity for further development of robust multi-criteria offer filters for all organs.

Public comment feedback was gathered on the proposal from September 17, 2024, to October 16, 2024. A town hall webinar was held on September 17, 2024, during which the MPSC Chair described the proposal and participated in an extensive question and answer session. At its November 6 – 8, 2024 meeting, the Committee reviewed the public comment response and voted to approve sending the proposal with no post-public comment changes (other than the correction of a couple of typographical errors) to the OPTN Board of Directors for approval at its November 21, 2024, meeting.

OPO Performance Monitoring Enhancements

The OPO Performance Monitoring Enhancement Workgroup developed an OPO referral data capture module that incorporates logic, standard processes, and consistent definitions. The OPTN would partner with electronic donor record vendors to incorporate the module into their systems. The resulting data would then be electronically transferred to the OPTN Computer System. The Committee approved the release of 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 used to validate data submitted by OPOs as a demonstration project for future data collection from all donor hospitals.³

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 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) and therefore, all workgroup and Committee work ceased on this project.

The 60-day Federal Register notice of an Information Request Package (ICR) for the federal Office of Management and Budget (OMB) was released on November 4, 2024. The Workgroup will be working with the OPTN Data Advisory Committee to develop a draft OPTN public comment for consideration by the OPTN Executive Committee.

Recently, the Committee requested data from the SRTR on its development of risk adjusted OPO performance metrics in order to consider alternative interim metrics the Committee could use until sufficient data is collected pursuant to the HRSA Data Directive to develop new metrics. The SRTR will present its work on these performance metrics to the MPSC OPO Performance Monitoring Enhancement Workgroup in the near future.

³ 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.

Membership Requirements Revision

The Committee resumed work on the Membership Requirements Revision project in spring 2024. The Committee is conducting a comprehensive review of all of the OPTN membership requirement policies 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 policies are in compliance with the OPTN Final Rule, address inconsistencies in the policies, 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 Policies. 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.

The Committee reviewed the 2021 proposal and discussed 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 voted 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 summer 2024 public comment. Simultaneously, the Histocompatibility Committee is sponsoring a proposal that includes revisions to *Appendix C Membership Requirements for Histocompatibility Laboratories* that was released for public comment this summer. At the July meeting, HRSA informed the Committee that the MPSC proposal would not be released for summer 2024 public comment. The Committee ceased all work on membership requirements revisions following this announcement.

HRSA later indicated that their concern was with the membership application and review process contained in the proposed *Appendix A*. HRSA indicated that the application review process is part of the awarded *Improving Patient Safety Task* to review the patient safety and policy compliance systems and processes. HRSA supported the Committee resuming work on the membership requirements if the Committee leadership believed this work was a priority to address identified issues with membership requirements. The Committee reviewed and voted to approve release of a proposal for revisions to *Appendix B Membership Requirements for Organ Procurement Organizations (OPOs)*, and *Appendix D Membership Requirements for Transplant Hospitals and Transplant Programs* for winter 2025 public comment. *Appendix A Membership Application and Review* and other references to the proposed change to the application and review process has been removed from the proposal. The Committee will

also resume work on the organ-specific key personnel training and experience requirements in *Appendices E – J* of the *OPTN Management and Membership Policies*.

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

Programs were required to submit an attestation that they were in compliance with *OPTN Policy 3.7.D* eGFR requirements by January 3, 2024. As of January 4, 2024, all kidney programs had submitted their attestations. However, HRSA raised concerns over programs that submitted an attestation but did not submit any or only submitted a few waiting time modifications while having Black or African American candidates on their waiting lists. 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 race inclusive eGFR calculation. The MPSC was tasked with identifying a plan and threshold for further inquiry with kidney programs that may raise these concerns.

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 determined that they would inquire with the bottom 25th percentile, which would include any programs with 20 percent or less modifications. During its March 29, 2024, meeting, the MPSC reviewed 56 member 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 reviewed additional information on those 11 programs at its July meeting. The 11 programs provided clarification or information about re-reviewing their waitlisted patients for eligibility. The Committee agreed that nine of the 11 program reviews could close with no further action. The other two received an additional specific inquiry and were reviewed at the November 2024 meeting. The MPSC determined that these programs now complied with the policy and closed the review with no action. Further review and education on this policy will occur as part of routine monitoring.

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 policy referrals, are discussed at the conclusion of each MPSC multi-day meeting and are sent to the respective OPTN Committees with a two-month response window. To date, there have been 12 MPSC referrals to six OPTN committees, with two new referrals from the November meeting to be shared with relevant committees soon. Referrals with updates in the past six months are detailed below. Details on the referrals without updates from the past six months can be found in the June 2024 MPSC Report to the OPTN Board of Directors.⁴

⁴ MPSC Report to the Board of Directors, June 2024, OPTN, https://optn.transplant.hrsa.gov/media/iwradpt5/20240612_mpsc_report-to-the-board.pdf.

The MPSC referred six new projects following the February 16-17, 2023, meeting. Three of the six referrals have had updates in the past six months:

Standardize Reporting Information to Patient Safety Contacts

The Ad Hoc Disease Transmission Advisory Committee (DTAC) developed a proposal to modify requirements for Patient Safety Contacts and communicating test results. This work was done in collaboration from the DTAC, MPSC, Data Advisory (DAC), OPO, and Transplant Administrators (TAC) Committees. This proposal was approved by the OPTN Board of Directors on June 17, 2024. The language in *OPTN Policy 15.1 Patient Safety Contact* requiring a primary and secondary Patient Safety Contact was implemented on July 25, 2024, and the remaining policy language and audit is slated for implementation in spring 2025.

Clarify Requirements for Reporting Post-Transplant Diseases

This project began in early 2024 and has been split into two phases. Phase one is 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.

Consider Clarifying DCD Conflicts of Interest Policies

Starting in July 2023, the 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 approved by the OPTN Board of Directors on June 17, 2024, and implemented on July 25, 2024.

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

Introduce Pre/Post Transfusion Field

The MPSC referred the inclusion of a checkbox, or a like data collection method, to standardize how blood typing information is communicated between OPOs and transplant programs. The Operations and Safety Committee (OSC) has decided to include this data element into their review of Deceased Donor Testing Requirements, which was approved by the OPTN Executive Committee on June 14, 2024, and is slated for summer 2025 public comment. The workgroup began meeting in August 2024 and includes representatives from the OSC, DTAC, MPSC, TAC, Transplant Coordinators (TCC), OPO, Histocompatibility, Heart, Kidney, Pancreas, and Liver Committees.

The MPSC referred two new projects following the November 1-3, 2023, meeting. One referral has had an update in the past six months:

Transportation Events

While initially jointly referred to the OSC and 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. The OSC was hoping to obtain ancillary qualitative information from

the “Late Declines Discovery Project” sponsored by the OPTN Expeditious Taskforce to inform next steps. With the pause of this part of the Expeditious Taskforce’s work and the prioritization of other work by the OSC, this project is currently slated behind other projects the OSC is undertaking.

The MPSC referred three new projects following the March 5-7, 2024, meeting. Two referrals have had an update in the past six months:

Late Declines

The OPO Committee is supportive of this work and eager to take it on, but like the transportation events referral the OPO Committee was hoping to obtain ancillary qualitative information from the “Late Declines Discovery Project” sponsored by the OPTN Expeditious Taskforce to inform next steps. With the pause of this part of the Expeditious Taskforce’s work and the prioritization of other work by the OPO Committee, this project is currently slated behind other projects they are undertaking.

eGFR Monitoring

Following the MPSC’s extensive compliance review of the eGFR implementation, this referral was aimed at standardizing the ways in which transplant programs apply and comply with *OPTN Policies 1.2 Glomerular Filtration Rate (GFR) and 3.7.D Waiting Time modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations*. 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 and support from MPSC members. The OPTN Executive Committee approved this project on August 29, 2024, and it is currently slated for winter 2025 public comment.

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.⁵ 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.⁶ Since then, the MPSC has shared six messages to the community:

- Donation after circulatory death (DCD) protocols and managing multiple organs (December 2022)⁷
- Reducing risk and ensuring patient safety (July 2023)⁸

⁵ MPSC Resources, OPTN, <https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/mpsc-resources/>.

⁶ Executive Committee Meeting Summary, December 4, 2022, OPTN, https://optn.transplant.hrsa.gov/media/emgbm4a0/20221204_excom_meeting-summary.pdf.

⁷ 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/>.

⁸ 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/>.

- Implementation of the Offer Acceptance performance metric and other recommendations (October 2023)⁹
- Upcoming eGFR waiting time modifications deadline and other updates (December 2023)¹⁰
- Reporting Patient Safety events, DCD organ recovery pre-OR huddles, and other recommendations (April 2024)¹¹
- Best practices for organ verification and other recommendations (September 2024)¹²

At the conclusion of each multi-day meeting, the MPSC will determine what key takeaways from the meeting are essential to share with the community to improve practices, promote quality initiatives, 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. There is also a desire for a process map for events that are reported to the OPTN Patient Safety Reporting Portal and 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.¹³ This page and its documents are updated annually with the next update occurring in August 2024.

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. 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.¹⁴

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

⁹ 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/>.

¹⁰MPSC 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/>.

¹¹ 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/>.

¹² MPSC Chair Communication, September 2024, OPTN, <https://optn.transplant.hrsa.gov/news/an-important-message-from-the-mpsc-on-best-practices-for-organ-verification-and-other-recommendations/>.

¹³ Compliance and Evaluation, OPTN, <https://optn.transplant.hrsa.gov/policies-bylaws/compliance-and-evaluation/>.

¹⁴ MPSC Report to the Board, December 2022, OPTN, https://optn.transplant.hrsa.gov/media/ojenbrcm/20221205_mpsc_report-to-the-board.pdf.

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

MPSC Resources Page

Access Dates	Page Views	Events
3/1/2023 - 9/30/2024	2361	6718

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	179	467
2	7/7/2023	7529	46%	316	7/7/2023	175	440
3	10/6/2023	7713	37%	505	10/6/2023	267	705
4	12/8/2023	7711	43%	871	12/8/2023	127	380
5	4/15/2024	8518	30%	408	4/15/2024	301	864
6	9/19/2024	8528	41%	623	9/19/2024	285	854

Data through 9/30/2024

Educational Efforts

MPSC and OPTN Contractor staff work together to share 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, 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 multi-day meeting conclusion. The MPSC recently collaborated with DTAC on an OPTN statement published in September regarding the blood culture bottle shortage impacting the community.

Appendix A includes MPSC-related posters and presentations that occurred from June 2024 – November 2024.

Monitoring Activities

The charts below detail the various types and outcomes of MPSC monitoring activities between June 2024 and November 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, and most recently reviewed and approved all current rules at its November 2024 meeting. The ongoing review of operational rules makes it possible to consistently improve the MPSC's process and the impact on patients.

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 Management and Membership Policies*, 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 Performance 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 was implemented in July 2024. The definition of these metrics is contained in the *OPTN Management and Membership Policies, Appendix D, Section D.12*.

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 1 below shows the total number of submissions reviewed by the MPSC from June – November 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 1: Number of Transplant Program Performance Submissions Reviewed

MPSC Action	Program Type					Total
	Heart	Kidney	Liver	Lung	Pancreas	
Send initial inquiry	20	9	12	7	1	49
Continue to monitor	17	33	21	17	4	92
Skip a cycle	0	5	1	3	0	9
Informal discussions (held)	1	3	0	1	0	5
Informal discussions (offer pending)	0	2	1	1	0	4
Peer visit	0	0	1	1	0	2
Request to inactivate	0	0	1	0	0	1
Released	22	11	13	5	2	53

Functional Inactivity

As required by the *OPTN Management and Membership Policies, Appendix D, Section D.11*, the MPSC periodically reviews transplant program functional inactivity. **Table 2** outlines the triggers for functional inactivity review if the program does not perform a transplant during the stated period:

Table 2: 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"> 1. Failure to perform at least 2 transplants in 12 consecutive months 2. Either of the following in 12 consecutive months: <ol style="list-style-type: none"> a. A median waiting time of the program’s K/P and pancreas candidates that is above the 67th percentile of the national waiting time b. The program had no K/P or pancreas candidates registered at the program
Stand-alone pediatric transplant programs	12 consecutive months

Table 3 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 3: Number of Transplant Program Functional Inactivity Submissions Reviewed

MPSC Action	Program Type					Total
	Heart	Kidney	Liver	Lung	Pancreas	
Send initial inquiry	0	0	0	0	0	0
Continue to monitor	0	0	0	2	2	4
Skip a cycle	0	0	0	0	0	0
Informal discussions (held)	0	0	0	0	0	0
Informal Discussions (offer pending)	0	0	0	0	0	0
Request to inactivate	0	0	0	0	0	0
Released	1	1	1	0	1	4

OPO Organ Yield

As required by the *OPTN Management and Membership Policies 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.

Table 4: Number of OPO Organ Yield Submissions Reviewed

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

Compliance Reviews

References to compliance reviews include site surveys, investigations, and allocations reviews. As outlined in the *OPTN Management and Membership Policies*, 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

Table 5 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 5: Compliance Reviews and MPSC Actions

MPSC Action		Allocation Reviews	Site Surveys	Investigations
Action	Close with no action	46	31	58
	Follow up survey	n/a	14	n/a
	Notice of Noncompliance	0	1	66
	Letter of Warning	0	0	0
	Probation	0	0	0
	Member Not in Good Standing	0	0	0
Interactions	Informal Discussions (held)	0	1	6
	Informal Discussions (offer pending)	0	0	3
	Interviews (held)	0	0	1
	Interviews (offer pending)	0	0	0
	Peer Visit	0	1	2

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. The MPSC has noted a significant increase in the number of OPO allocations out of sequence (AOOS), and the Committee has formed a subcommittee to evaluate potential changes and improvements to the MPSC's review of allocations information to identify the most concerning patterns or trends.

Table 5 above notes 46 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, simultaneous liver kidney 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 5 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 Baseline 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 Electronic Medical Record (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 and Patient Safety Reporting

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.

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. OPTN Contractor staff escalate reports of certain events to MPSC leadership and HRSA as required by the “HRSA-required event reporting” 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 is supported by the information provided by the member 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 non-compliance exists. At the conclusion of the investigation, investigative staff present their findings and recommendations to an interdisciplinary committee to reach consensus on next steps. If the investigation shows evidence of a potential non-compliance, OPTN Contractor staff forward the investigation results to the MPSC for review. If the investigation is unable to discover information to support 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 reports of investigative activity to the MPSC at every meeting as well as HRSA on a monthly cadence. 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 investigative 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 or not under purview of OPTN policy, and lack of reporter follow-up with investigators. After reviewing the report, MPSC members may request to view a closed case for a more in-depth look at the issue.

Table 6 below shows that from June 1, 2024, to October 27, 2024, 123 of the 250 reports received by Patient Safety were not forwarded to the MPSC for review. 37 of the reports were referred to other OPTN Contractor departments as they routinely monitor this type of activity, such as site survey. 35 reports were reviewed and cleared, meaning these events were investigated without the need for additional member inquiry and determined to be outside of OPTN purview, does not violate OPTN policy, or were not a Patient Safety issue. 51 reports were investigated and determined to not violate OPTN Policy or pose a threat to patient safety. 13 reports were investigated and found to potentially violate OPTN policy and were referred to the MPSC for further review. 114 reports are under active staff investigation. Efforts are underway to reduce the number of active investigations.

Table 6: Patient Safety Reporting

Reporting Method	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	TOTAL 6/1/2024 - 10/27/2024
OPTN Patient Safety Reporting Portal	34	43	39	46	34	196
Other OPTN Contractor Staff (Allocations, Patient Services, Disease Transmission, Whistleblower/Special Council)	6	7	8	11	4	36
Member Reporting Line	1	0	2	1	3	7
Automated Reports (Potential HIV+ Transplants in Past 24 Hours, Multiple listings, Different ABO)	2	0	1	1	0	4
Phone	0	0	1	0	2	3
Email	0	1	1	0	0	2
Media	0	0	0	1	0	1
Fax or Letter	0	1	0	0	0	1
Total Reports	43	52	52	60	43	250
Reviewed and Cleared	10	7	12	3	3	35
Closed	11	13	15	9	3	51
Under Active Investigation	9	14	20	37	34	114
Referred to Other OPTN Contractor Staff	7	15	3	9	3	37
Referred to MPSC	6	3	2	2	0	13

The 250 reports were categorized across several primary classifications, as shown in **Table 7** below. Organ and Extra Vessels reported the highest volume with 44 reports, addressing issues related to organ and extra vessel packaging, labeling, shipping, and laterality. Deceased Donor Organ Procurement followed with 40 reports, reflecting steady reporting in this area. The spike in Allocation reports in July, with 15 total reports, was largely driven by a single program that submitted 10 reports. These reports involved allegations of being bypassed by different OPOs, which were subsequently referred to the Allocations team for routine monitoring. The "Other" category, with 38 reports, includes events that do not specifically fit into other primary classifications. This category includes events that may identify systemic issues, such as member-specific allegations involving outcomes, patient care, staffing issues, and unprofessional conduct. Organ Offers Acceptance and Verification received 24 reports, with moderate consistency across the months. Identification of Transmissible Diseases and Living Donation both reported 21 cases, with noticeable activity in August and October for transmissible diseases. Remaining categories, including Candidate Registrations Modifications and Removals, ABO, and Histocompatibility, reported fewer cases, indicating fewer incidents in these areas.

Table 7: Patient Safety Case Classifications

Primary Classification	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	TOTAL 6/1/2024 - 10/27/2024
Organ and Extra Vessels	10	8	10	12	4	44
Deceased Donor Organ Procurement	4	6	11	12	7	40
Other	8	7	6	8	9	38
Allocation	4	15	2	5	3	29
Organ Offers Acceptance and Verification	6	5	3	4	6	24
Identification of Transmissible Diseases	3	3	7	6	2	21
Living Donation	4	2	5	4	6	21
Candidate Registrations Modifications and Removals	3	2	3	3	2	13
ABO	1	3	1	4	1	10
Histocompatibility	0	1	4	2	3	10
TOTALS	43	52	52	60	43	250

Of the 250 reports received by the OPTN Contractor this cycle, 16 of those reports met “HRSA-required event reporting” (Since 2011, HRSA and the OPTN have identified certain events that could pose a serious risk to patient health, public safety, or the integrity of the transplant system. If a suspected event is determined to be a HRSA-Required Reporting Event, the OPTN Contractor Investigator is required to notify HRSA within 24-hours of becoming aware of the event) and were communicated to HRSA, MPSC leadership, OPTN President, OPTN Vice President, and immediate past OPTN President as required by contract. This is an increase in HRSA reportable events from the last MPSC Report to the Board of Directors (12), especially given five fewer weeks of data recorded over this cycle. One factor in the increase is due to the rise in suspected HIV and Non-HIV disease transmission events, as well as a moderate increase in the reports that may pose a serious or time-sensitive threat to public health or patient safety regardless of whether there is a suspected or actual violation of OPTN policy.

Network Operations Oversight Committee (NOOC) Referrals to the MPSC

At its meeting on September 23, 2024, NOOC referred to the MPSC three members that had failed to meet the attestation requirement according to *OPTN Policy 3.1.A, Security Requirements for Systems Accessing the OPTN Computer System*. On October 4, 2024, OPTN Contractor staff sent inquiry letters to the three members on behalf of the MPSC with a final attestation submission due date of October 18, 2024. By October 17, 2024, the three members submitted their attestations thereby meeting the requirement in *Policy 3.1.A*. OPTN Contractor staff closed these three cases on behalf of the MPSC per the MPSC’s decision at its July 2024 meeting to close cases that came into compliance during the inquiry phase.¹⁵

¹⁵ MPSC Meeting Summary, July 2024, OPTN, https://optn.transplant.hrsa.gov/media/423fsumo/20240723_mpsc_meeting-summary_public.pdf

Donor Acceptance Criteria

In March of 2024, OPTN Contractor staff identified the use of narrow donor acceptance criteria by some transplant programs was significantly limiting active candidates' chances of receiving organ offers. In response, detailed data was compiled and shared with the MPSC, highlighting variations in criteria usage across program types, transplant hospitals, and specific criteria values. This data-driven approach provided insights into how acceptance practices differ across the system, informing future actions.

Additionally, MPSC leadership discussed the issue during their meetings on May 14th, July 16th, October 22nd, and October 30th continuing to monitor and guide the investigation. The full MPSC met on September 17th to review these findings and determine which hospitals and programs would receive inquiry letters.

The ongoing investigation may result in referrals to other OPTN committees for the development of new policy or guidance documents. These efforts aim to promote more consistent practices, increase organ acceptance, and improve match efficiency, ensuring fair access to transplantation for all candidates.

Membership Applications

The MPSC monitors compliance with OPTN membership requirements, including new member applications. **Table 8** below summarizes the different types of applications reviewed from June 2024 through November 2024. 281 applications were reviewed, a slight decrease from the 292 applications reviewed during the same timeframe in 2023. This difference is attributed to fewer new transplant program or component applications and fewer transplant program long term inactivations and withdrawals.

The MPSC reviewed a total of 602 applications from December 2023 through November 2024, 74 less than the previous twelve-month cycle.¹⁶ While the volume of key personnel applications increased in 2024, almost all other application types related to program or membership status showed a small decrease in volume.

¹⁶ MPSC Report to the Board, December 2023, OPTN, https://optn.transplant.hrsa.gov/media/i11oj3v5/20231129_mpsc_report-to-the-board.pdf

Table 8: Number and Type of MPSC Application Reviews

Type of Application	Number
Transplant Hospitals and Programs	
New Transplant Hospitals	0
New Programs and Components	12
Key Personnel Applications	191
Program and Component Conditional Approvals	3
Conditional to Full Approvals	4
Conditional Extensions	0
Program and Component Long Term Inactivations	8
Inactivation Extensions	1
Program and Component Reactivations	7
Program and Component Withdrawals	6
Transplant Hospital Withdrawals	0
Organ Procurement Organizations (OPOs)	
OPO Key Personnel Change Notifications	6
OPO Merges	1
Histocompatibility Labs	
New Histocompatibility Labs	0
Histocompatibility Lab Key Personnel Changes	29
Histocompatibility Lab Withdrawals	1
Non-Institutional Members	
New Non-Institutional Members	7
Non-Institutional Membership Renewals	4
Non-Institutional Membership Withdrawals	1
TOTAL	281

Data through 11/8/2024

Additional OPTN Contactor Staff-Led Improvement Activities

Individual Member Focused Improvement

The Individual Member Focused Improvement (IMFI) initiative is designed to help individual members improve through tailored quality improvement tools and engagements custom designed to address their specific needs. After a three-year discovery and design phase that included pilot projects informed by the MPSC, IMFI officially launched broad deployment on October 1, 2022. Each IMFI engagement is customized to align with the member’s specific project improvement goal. The initiative is available to members who receive notification that their program is in the “yellow zone” for OPTN post-transplant graft survival, offer acceptance, and pre-transplant mortality metrics.

From June 2024 to November 2024, four new IMFI engagements were initiated, five IMFI engagements were completed, and no projects were ongoing as of November 1, 2024. Participants included kidney, liver, and lung transplant programs. Members participated in training and education components throughout their engagement focused on the OPTN Learning Management System’s OPTN Data Services tools and resources.

Appendix A: Posters and Presentations

Title	Presenter(s)	Type of Presentation	Conference/ Meeting	Description
MPSC Insights Into Program Performance	Cliff Miles, MD, MPSC Chair	Presentation	Transplant Quality Institute	This presentation highlighted information regarding MPSC member review processes and performance metrics, including the pre-transplant morality metric implemented in July 2024, along with the proposed changes to the post-transplant outcome review thresholds.

Appendix B: Monitoring Effectiveness Baseline Report



Contract: HSH250-2019-00001C
Task: 3.6.2
Item: A140
Due: 10 business days prior to each MPSC multi day meeting
Submitted: October 23rd, 2024

Monitoring Effectiveness Baseline Report

PWS Excerpt:

3.6.2

The Contractor shall measure effectiveness of the processes used to identify compliance, encourage improvement, and determine sanctions

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.

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

Table 1. Quantity of deceased donor organ allocations resulting in a transplant wherein a deviation of allocation policy occurred, by type of organ, type of deviation and fiscal quarter during which the deviation took place April 01, 2022 - March 31, 2024.

Organ Type	Fiscal Quarter	Total	Allocation Out of Sequence	Allocation Out of Sequence %	Directed Donations	Direct Donations %	Clean	Clean %
All Combined	FY2022 Q3	9,192	918	9.99%	95	1.03%	8,179	88.98%
	FY2022 Q4	9,721	1,031	10.61%	70	0.72%	8,620	88.67%
	FY2023 Q1	9,676	1,122	11.60%	72	0.74%	8,482	87.66%
	FY2023 Q2	9,678	1,325	13.69%	60	0.62%	8,293	85.69%
	FY2023 Q3	10,580	1,598	15.10%	68	0.64%	8,914	84.25%
	FY2023 Q4	10,249	1,514	14.77%	76	0.74%	8,659	84.49%
	FY2024 Q1	10,115	1,721	17.01%	64	0.63%	8,330	82.35%
	FY2024 Q2	10,287	1,841	17.90%	63	0.61%	8,383	81.49%
	<i>Total over all quarters</i>	79,498	11,070	13.92%	568	0.71%	67,860	85.36%
HR	FY2022 Q3	1,022	22	2.15%	3	0.29%	997	97.55%
	FY2022 Q4	1,100	29	2.64%	0	0.00%	1,071	97.36%
	FY2023 Q1	1,113	29	2.61%	0	0.00%	1,084	97.39%
	FY2023 Q2	1,081	33	3.05%	0	0.00%	1,048	96.95%
	FY2023 Q3	1,219	38	3.12%	0	0.00%	1,181	96.88%
	FY2023 Q4	1,203	45	3.74%	2	0.17%	1,156	96.09%
	FY2024 Q1	1,102	41	3.72%	0	0.00%	1,061	96.28%
	FY2024 Q2	1,070	56	5.23%	0	0.00%	1,014	94.77%
	<i>Total over all quarters</i>	8,910	293	3.29%	5	0.06%	8,612	96.66%
IN	FY2022 Q3	22	2	9.09%	0	0.00%	20	90.91%
	FY2022 Q4	22	3	13.64%	0	0.00%	19	86.36%
	FY2023 Q1	22	0	0.00%	0	0.00%	22	100.00%
	FY2023 Q2	17	0	0.00%	1	5.88%	16	94.12%
	FY2023 Q3	29	1	3.45%	0	0.00%	28	96.55%
	FY2023 Q4	23	0	0.00%	0	0.00%	23	100.00%
	FY2024 Q1	26	1	3.85%	0	0.00%	25	96.15%
	FY2024 Q2	21	1	4.76%	0	0.00%	20	95.24%
	<i>Total over all quarters</i>	182	8	4.40%	1	0.55%	173	95.05%
KI	FY2022 Q3	5,020	577	11.49%	79	1.57%	4,364	86.93%
	FY2022 Q4	5,333	673	12.62%	64	1.20%	4,596	86.18%
	FY2023 Q1	5,293	773	14.60%	58	1.10%	4,462	84.30%
	FY2023 Q2	5,238	899	17.16%	49	0.94%	4,290	81.90%
	FY2023 Q3	5,689	1,027	18.05%	56	0.98%	4,606	80.96%
	FY2023 Q4	5,518	1,005	18.21%	65	1.18%	4,448	80.61%
	FY2024 Q1	5,398	1,108	20.53%	60	1.11%	4,230	78.36%
	FY2024 Q2	5,491	1,221	22.24%	51	0.93%	4,219	76.83%
	<i>Total over all quarters</i>	42,980	7,283	16.95%	482	1.12%	35,215	81.93%

Organ Type	Fiscal Quarter	Total	Allocation Out of Sequence	Allocation Out of Sequence %	Directed Donations	Direct Donations %	Clean	Clean %
LI	FY2022 Q3	2,206	258	11.70%	13	0.59%	1,935	87.72%
	FY2022 Q4	2,298	283	12.32%	5	0.22%	2,010	87.47%
	FY2023 Q1	2,306	276	11.97%	10	0.43%	2,020	87.60%
	FY2023 Q2	2,384	338	14.18%	8	0.34%	2,038	85.49%
	FY2023 Q3	2,537	406	16.00%	10	0.39%	2,121	83.60%
	FY2023 Q4	2,486	380	15.29%	9	0.36%	2,097	84.35%
	FY2024 Q1	2,606	462	17.73%	4	0.15%	2,140	82.12%
	FY2024 Q2	2,668	453	16.98%	12	0.45%	2,203	82.57%
	<i>Total over all quarters</i>	19,491	2,856	14.65%	71	0.36%	16,564	84.98%
LU	FY2022 Q3	705	45	6.38%	0	0.00%	660	93.62%
	FY2022 Q4	696	27	3.88%	0	0.00%	669	96.12%
	FY2023 Q1	710	36	5.07%	2	0.28%	672	94.65%
	FY2023 Q2	731	46	6.29%	0	0.00%	685	93.71%
	FY2023 Q3	844	111	13.15%	0	0.00%	733	86.85%
	FY2023 Q4	784	66	8.42%	0	0.00%	718	91.58%
	FY2024 Q1	766	95	12.40%	0	0.00%	671	87.60%
	FY2024 Q2	832	101	12.14%	0	0.00%	731	87.86%
	<i>Total over all quarters</i>	6,068	527	8.68%	2	0.03%	5,539	91.28%
PA	FY2022 Q3	217	14	6.45%	0	0.00%	203	93.55%
	FY2022 Q4	272	16	5.88%	1	0.37%	255	93.75%
	FY2023 Q1	232	8	3.45%	2	0.86%	222	95.69%
	FY2023 Q2	227	9	3.96%	2	0.88%	216	95.15%
	FY2023 Q3	262	15	5.73%	2	0.76%	245	93.51%
	FY2023 Q4	235	18	7.66%	0	0.00%	217	92.34%
	FY2024 Q1	217	14	6.45%	0	0.00%	203	93.55%
	FY2024 Q2	203	9	4.43%	0	0.00%	194	95.57%
	<i>Total over all quarters</i>	1,865	103	5.52%	7	0.38%	1,755	94.10%

Table 1 shows the number of organ allocations resulting in a transplant that deviated from organ allocation policy between April 01, 2022 and March 31, 2024. 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"). This also includes allocations where the recipient was not on the match run, local backups, and any other type of deviation from organ allocation policy. Many of the Organ Groups have increasing "Allocation out of Sequence". As a result of this finding, the OPTN Membership and Professional Standards Committee (MPSC) created a workgroup to look at the root causes of the uptick in allocations out of sequence as well as how to change MPSC review to mitigate the increase in this trend. 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 submitted to be reviewed by the MPSC April 01, 2023 - March 31, 2024.

Fiscal Quarter	Number of Cases	Pending	Pending %	Submitted	Submitted %	Not Submitted	Not Submitted %
FY2023 Q3	130	7	5.38%	48	36.92%	75	57.69%
FY2023 Q4	152	4	2.63%	46	30.26%	102	67.11%
FY2024 Q1	131	6	4.58%	49	37.40%	76	58.02%
FY2024 Q2	156	23	14.74%	43	27.56%	90	57.69%

Table 2 shows the number of patient safety event cases processed by Compliance and Safety Investigators (CSIs) between April 01, 2023 and March 31, 2024, and whether cases were submitted to be reviewed by 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 submit the case for review by 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." April 01, 2022 - March 31, 2024.

Fiscal Quarter	Total Number of Responses	Agree or Strongly Agree	Agree or Strongly Agree %	Disagree or Strongly Disagree	Disagree or Strongly Disagree %
FY2022 Q3	17	16	94.12%	1	5.88%
FY2022 Q4	22	22	100.00%	0	0.00%
FY2023 Q1	19	19	100.00%	0	0.00%
FY2023 Q2	15	15	100.00%	0	0.00%
FY2023 Q3	16	15	93.75%	1	6.25%
FY2023 Q4	16	16	100.00%	0	0.00%
FY2024 Q1	19	18	94.74%	1	5.26%
FY2024 Q2	10	10	100.00%	0	0.00%
Totals over all quarters	134	131	97.76%	3	2.24%

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 April 01, 2022 and March 31, 2024: 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 April 01, 2022 - March 31, 2024.

Fiscal Quarter	Members with a compliance issue resulting in an MPSC action	Members with a compliance issue resulting in an MPSC action and another within 12 months	% of Members with a compliance issue resulting in an MPSC action and another within 12 months	Members with a compliance issue resulting in an MPSC action but no other action within 12 months
FY2022 Q3	3	1	33.33%	2
FY2022 Q4	31	0	0.00%	31
FY2023 Q1	32	0	0.00%	32

Table 4 shows the number of members between April 01, 2022 and March 31, 2024, 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 FY2023 Q1 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 component, and organ procurement organization policy compliance rates, subset by policy and associated organ type, April 01, 2022 - March 31, 2024.

Member Type	Organ	Policy	Type	Total number of items	Compliant	Compliant %	Not Compliant	Not Compliant %
OPO	OPO	2.2 #2	Records	545	545	100.00%	0	0.00%
		2.2 #5	Records	545	545	100.00%	0	0.00%
		2.2 #14	Records	545	530	97.25%	15	2.75%
		2.2 #15	Records	575	573	99.65%	2	0.35%
		2.3	Records	535	535	100.00%	0	0.00%
		2.4	Records	543	543	100.00%	0	0.00%
		2.5	Records	545	542	99.45%	3	0.55%
		2.6.B	Records	165	163	98.79%	2	1.21%
		2.8 #7	Records	543	540	99.45%	3	0.55%
		2.9 #2	Records	545	545	100.00%	0	0.00%
		2.11.B #2c (LI)	Records	370	368	99.46%	2	0.54%
		2.11.E #5 & #6 (PA)	Records	40	40	100.00%	0	0.00%
		2.14.B	Records	545	529	97.06%	16	2.94%
		2.14.C #6	Records	550	534	97.09%	16	2.91%
		15.4.A	Records	545	538	98.72%	7	1.28%
		16.5	Records	545	541	99.27%	4	0.73%
		18.1 (Accuracy DDRs)	Elements	25,850	25,619	99.11%	231	0.89%
		18.1 (noneligible)	Records	215	188	87.44%	27	12.56%
		Accuracy of DonorNet	Elements	10,300	10,239	99.41%	61	0.59%
		Accuracy of Serologies	Records	560	554	98.93%	6	1.07%

Member Type	Organ	Policy	Type	Total number of items	Compliant	Compliant %	Not Compliant	Not Compliant %
Transplant Recipient	HR	5.10.E	Records					
		5.10.E DEE	Records					
		6.1	Listings	1,220	1,202	98.52%	18	1.48%
		6.1/6.2/6.3/6.4 DEE	Listings	2,208	2,122	96.11%	86	3.89%
		6.2	Listings	340	340	100.00%	0	0.00%
		6.4	Listings	700	700	100.00%	0	0.00%
	KI	5.3.C	Records	752	708	94.15%	44	5.85%
		8.3	Listings	1,476	1,441	97.63%	35	2.37%
		8.3 DEE	Listings	1,505	1,478	98.21%	27	1.79%
		8.4.A	Records	1,093	1,075	98.35%	18	1.65%
		8.4.D	Records	116	113	97.41%	3	2.59%
		8.4.F	Records	106	106	100.00%	0	0.00%
		8.4.G	Records	1	1	100.00%	0	0.00%
		8.4.G DEE	Records	1	1	100.00%	0	0.00%
		8.4.H	Records					
		8.4.H DEE	Records					
		8.4.I	Records					
		8.4.I DEE	Records					
		LI	9.1.(A-E)/9.5 DEE	Listings	2,313	2,231	96.45%	82
	9.1.A/9.1.B/9.1.C/9.2		Listings	366	357	97.54%	9	2.46%
	9.1.D		Listings	261	256	98.08%	5	1.92%
	9.1.E		Listings	11	11	100.00%	0	0.00%
	9.2		Listings	156	155	99.36%	1	0.64%
	9.5		Listings	46	45	97.83%	1	2.17%
	9.5/9.2		Listings	1,612	1,590	98.64%	22	1.36%
	9.9		Records	268	265	98.88%	3	1.12%
	9.9 DEE		Records	265	247	93.21%	18	6.79%
	LU	5.10.F	Records	1	1	100.00%	0	0.00%
		10.1	Listings	1,450	1,254	86.48%	196	13.52%
		10.1 DEE	Listings	1,360	1,315	96.69%	45	3.31%
		10.1.A/10.1.B/10.1.C	Listings	27	24	88.89%	3	11.11%
		10.3	Records	129	125	96.90%	4	3.10%
	Non-specified	5.8.B	Records	5,148	5,006	97.24%	142	2.76%
15.2		Records	4,750	3,427	72.15%	1,323	27.85%	
15.2 (TRR Accuracy)		Records	334	269	80.54%	65	19.46%	
15.3.B		Records	1,708	1,601	93.74%	107	6.26%	
15.3.C		Records	4,245	3,209	75.59%	1,036	24.41%	
18.1 Accuracy (TRF 6 mon..		Elements	5,088	3,928	77.20%	1,160	22.80%	
PA	11.3.B	Records	566	555	98.06%	11	1.94%	
	11.3.B DEE	Records	548	534	97.45%	14	2.55%	

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 April 01, 2022 and March 31, 2024. **Highlighted are policies with a greater than 5 percent non-compliance rate. Targeted education, 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. Of note: this requirement was removed from OPTN policy effective May 2, 2024. Members are no longer expected to comply with this requirement.

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, April 01, 2022 - March 31, 2024.

Member Type	Fiscal Quarter	Total Number of Programs Surveyed	Not recommended for Foc Desk	Not Recommended for Foc Desk %	Recommended for Foc Desk	Recommended for Foc Desk %
OPO	FY2022 Q3	3	2	66.67%	1	33.33%
	FY2022 Q4	5	3	60.00%	2	40.00%
	FY2023 Q1	3	3	100.00%	0	0.00%
	FY2023 Q2	6	6	100.00%	0	0.00%
	FY2023 Q3	5	4	80.00%	1	20.00%
	FY2023 Q4	5	5	100.00%	0	0.00%
	FY2024 Q1	5	5	100.00%	0	0.00%
	FY2024 Q2	2	1	50.00%	1	50.00%
	<i>Total over all quarters</i>		34	29	85.29%	5
Transplant Recipient	FY2022 Q3	71	29	40.85%	42	59.15%
	FY2022 Q4	78	34	43.59%	44	56.41%
	FY2023 Q1	75	38	50.67%	37	49.33%
	FY2023 Q2	46	21	45.65%	25	54.35%
	FY2023 Q3	47	18	38.30%	29	61.70%
	FY2023 Q4	46	22	47.83%	24	52.17%
	FY2024 Q1	46	19	41.30%	27	58.70%
	FY2024 Q2	68	41	60.29%	27	39.71%
	<i>Total over all quarters</i>		477	222	46.54%	255

Table 6 indicates the number and proportion of transplant recipient routine site surveys which were performed between April 01, 2022 and March 31, 2024 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.

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, April 01, 2022 - March 31, 2024.

Member Type	Fiscal Quarter	Total Number of Programs Surveyed	Not Recommended for Foc Desk	Not Recommended for Foc Desk %	Recommended for Foc Desk	Recommended for Foc Desk %
OPO	FY2022 Q3	1	1	100.00%	0	0.00%
	FY2023 Q2	3	1	33.33%	2	66.67%
	FY2024 Q2	1	1	100.00%	0	0.00%
	<i>Total for all quarters</i>	5	3	60.00%	2	40.00%
Transplant Recipient	FY2022 Q3	26	16	61.54%	10	38.46%
	FY2022 Q4	8	3	37.50%	5	62.50%
	FY2023 Q1	24	10	41.67%	14	58.33%
	FY2023 Q2	33	16	48.48%	17	51.52%
	FY2023 Q3	34	18	52.94%	16	47.06%
	FY2023 Q4	42	24	57.14%	18	42.86%
	FY2024 Q1	23	10	43.48%	13	56.52%
	FY2024 Q2	40	23	57.50%	17	42.50%
	<i>Total for all quarters</i>	230	120	52.17%	110	47.83%
Grand Total		235	123	52.34%	112	47.66%

Table 7 shows the proportion of focused desk reviews between 4/1/2022 - 3/31/2024 which resulted in either the MPSC or Member Quality recommending an additional follow-up focused desk review. Each quarter around 47.66% of programs (including LD components and OPOs) focused desk reviews resulted in an MPSC or MQ recommendation for an additional focused desk review.

Table 8. Proportion of members participating in at least two routine site surveys between January 01, 2018 - March 31, 2024 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	Item Type	Policy	No Desk - Decrease	No Desk - Same	No Desk - Increase	Yes Desk - Decrease	Yes Desk - Same	Yes Desk - Increase	% Yes Desk Increase - % No Desk Increase
OPO	OPO	Elements	Accuracy of DonorNet	15	11	9	0	0	1	
		Records	2.2 #2	0	35	0	0	1	0	
			2.2 #5	0	35	0	0	1	0	
			2.2 #14	5	16	14	1	0	0	
			2.2 #15	1	28	6	0	1	0	
			2.3	0	35	0	0	1	0	
			2.4	0	35	0	0	1	0	
			2.5	2	31	2	0	1	0	
			2.6.B	1	31	1	0	1	0	
			2.8 #7	1	28	6	0	0	1	
			2.9 #2	0	34	1	0	1	0	
			2.11.B #2c (LI)	3	30	2	0	1	0	
			2.11.E #5 & #6 (PA)	0	16	0	0	1	0	
			2.14.B	4	30	1	0	0	1	
			2.14.C #6	7	23	5	1	0	0	
			15.4.A	5	24	6	1	0	0	
			16.5	3	27	5	0	1	0	
			18.1 (noneligible)	7	11	7	1	0	0	
			Accuracy of Serologies	2	28	5	0	0	1	
		Total		56	508	70	4	11	4	10%

Member Type	Organ Type	Item Type	Policy	No Desk - Decrease	No Desk - Same	No Desk - Increase	Yes Desk - Decrease	Yes Desk - Same	Yes Desk - Increase	% Yes Desk Increase - % No Desk Increase
Transplant Recipient	HR	Listings	6.1	4	36	5	4	10	4	11%
			6.1/6.2/6.3/6.4 DEE	16	23	17	10	2	8	10%
			6.2	0	19	4	0	5	0	
			6.4	0	48	0	0	17	0	0%
			Total	20	126	26	14	34	12	5%
	KI	Listings	8.3	2	63	3	13	26	16	25%
			8.3 DEE	4	62	2	9	39	7	10%
			5.3.C	3	40	1	6	34	5	9%
		Records	8.4.A	4	61	1	7	43	3	4%
			8.4.D	1	7	0	1	15	0	
8.4.F			0	11	0	0	7	0		
Total	14	244	7	36	164	31	11%			
LI	Listings	9.1.(A-E)/9.5 DEE	12	17	17	11	7	18	13%	
		9.1.A/9.1.B/9.1.C/9.2	0	41	0	4	22	3	10%	
		9.5/9.2	4	29	3	7	14	7	17%	
	Records	9.9	0	23	0	0	28	1	3%	
		9.9 DEE	1	20	0	4	19	6	21%	
		Total	17	130	20	26	90	35	11%	
LU	Listings	10.1	5	0	5	3	0	4		
		10.1 DEE	3	2	3	1	0	6		
		Total	8	2	8	4	0	10	27%	
PA	Records	11.3.B	1	5	0	1	2	5		
		11.3.B DEE	0	5	1	1	4	3		
		Total	1	10	1	2	6	8	42%	
Non-specified	Records	5.8.B	11	183	28	14	27	96	57%	
		15.3.B	13	149	11	21	71	27	16%	
		Total	24	332	39	35	98	123	38%	

Table 8 shows the quantity of pairs of all routine site surveys where the member had two routine site surveys between January 01, 2018 and March 31, 2024 where a specific policy was reviewed. It compares the compliance rate of the first (2nd most recent) and second (most recent) surveys within those survey pairs for those policies, and indicates whether those rates decreased, increased or stayed the same. It also divides survey pairs into two cohorts based on whether a pair's first survey resulted in a recommendation for a desk review. The eighth column of the table indicates, for policies represented across at least 10 audits in both the Yes Desk and No Desk cohorts, the percentage point difference between cohorts in the proportion of survey pairs where compliance rate increased.