OPTN

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

Zoe Stewart Lewis, M.D., Ph.D., M.P.H., Chair December 5, 2022

The OPTN Membership and Professional Standards Committee (MPSC) is pleased to provide this report to the OPTN Board of Directors. This report reflects the work of the MPSC from December 2021 – November 2022. During that time, we have seen Congressional interest in the national organ donation and transplant system increase and heard calls for action on several fronts.

The MPSC is eager to work with OPTN membership, Congress, and other federal partners to address the concerns we have heard, increase public faith in the national system, provide essential clarification and context and, most importantly, drive improvement to best serve patients. Specifically, the MPSC will continue to seek opportunities to increase communication with the Centers for Medicare & Medicaid Services (CMS).

Additionally, the report summarizes the Committee's discussion of the National Academy of Science, Engineering and Medicine (NASEM) Ad Hoc Committee on A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation and Distribution's February 2022 report,¹ and the ongoing U.S. Senate Committee on Finance investigation.² The report also includes routine updates on the MPSC's project work, educational efforts, and monitoring activities.

NASEM Report

The MPSC's discussion of the NASEM report touched on a number of topics. As requested by the OPTN Policy Oversight Committee (POC), the MPSC will send a summary of its discussions to the POC for the POC to consider along with other OPTN Committees' feedback.

Key elements of the MPSC's discussion included, but were not limited to:

- the need to consider potential unintended consequences of and inherent tension between various efforts, such as the desire to simultaneously improve utilization and equity,
- possible improvements to transplant system metrics, including a project to revise the OPTN's organ procurement organization (OPO) performance metrics, and
- suggestions for various quality improvement efforts.

The MPSC noted that there are many objectives within the report, such as increasing utilization, access, equity, and outcomes, and that improvement in one area may negatively impact another. The Committee suggested the OPTN intentionally collect and evaluate data to understand the impact of

¹ National Research Council. 2022. Realizing the Promise of Equity in the Organ Transplantation System. Washington, DC: The National Academies Press. https://doi.org/10.17226/26364.

² A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network: Hearing before the U.S. Senate Committee on Finance, 117th Cong. (2022). https://www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network

different initiatives on each other. The MPSC noted this inherent tension is particularly evident during the Committee's review of allocations out of sequence and feels it is critical for the OPTN to develop standardized allocation practices for hard-to-place organs. As highlighted later in this report, the MPSC has observed a large increase in the number of allocations out of sequence. The MPSC noted that this increase coincides with an increase in organ utilization that may be driven by OPOs' development of practices to allocate hard-to-place organs using allocations out of sequence. The MPSC strongly supports rescue efforts to decrease cold ischemic time (CIT) and reduce the non-utilization rate. At the same time, the Committee believes it is important to study the potential impact these actions may have on access and equity to transplantation, and to develop a framework to try to promote consistent practices that strike the best balance among all desired objectives.

The MPSC discussed the report's suggestions to develop national performance goals and create dashboards of standardized metrics. The MPSC noted that current use of the "eligible donor" definition has limited potential with respect to expanding the pool of available donors and does not adequately measure OPO growth and performance. The MPSC also suggested a strategic metric to work towards, such as a certain number of donors per 100,000 population annually. The MPSC previously delayed plans for an OPO performance metrics revision project, to avoid establishing new OPTN performance metrics at the same time CMS was implementing new OPO performance metrics and review processes. The MPSC acknowledged that a key element of the project will include an assessment of how recent CMS OPO performance metrics should affect OPTN metrics. The MPSC would welcome any opinions from the Board of Directors on that topic, or any other suggested issues the Board would like the MPSC to consider. The MPSC plans to submit the project to the POC following this Board meeting and begin work on the project during its February 2023 meeting cycle.

The MPSC also discussed several ways to continuously improve upon current transplant program performance metrics. The OPTN Board of Directors approved the MPSC-sponsored proposal "Enhancing Transplant Program Performance Metrics" in December 2021. As noted in that proposal, the MPSC developed the metrics to evaluate programs based on multiple phases of patient care and create a more holistic approach to transplant program performance monitoring. As also noted in the proposal, the MPSC is committed to ongoing discussions about additional future improvements that can be implemented to best evaluate transplant program performance. When discussing the NASEM report, the MPSC noted the benefit of evaluating longer-term outcomes to increase the overall long-term survival rates of patients. The MPSC also discussed the benefit of studying carve-outs or different metrics for hard-to-place organs to try to increase utilization and save more lives. As noted throughout the MPSC's development of the transplant program performance measures project³, the community could likely benefit from ongoing education about how risk-adjustment models benefit programs that utilize marginal or typically hard-to-place organs and/or transplant recipients that are considered high risk for a variety of clinical reasons. The MPSC plans to incorporate evaluation of suggested carve-outs and publishing information on the factors that most often contribute to programs being identified for MPSC performance review into the Committee's evaluation of the new transplant program performance monitoring system.

³ Briefing to the OPTN Board of Directors on Enhance Transplant Program Performance Monitoring System, December 2021. <u>https://optn.transplant.hrsa.gov/media/yctffgt2/20211206-bp-mpsc-enhnc-tx-prgrm-prfrmnc-mntrng-syst.pdf</u>

The MPSC expressed support for the NASEM recommendation to embed continuous quality improvement efforts into the transplant system. The MPSC utilizes a variety of quality processes to help members improve compliance with various obligations and acknowledges the benefit of sharing lessons learned from those interactions with the community to proactively avoid compliance issues whenever possible. Though the MPSC has a duty to protect information shared and the integrity of the peer review system, it reaffirmed its commitment to finding ways to share more information about the causes behind never events and increase transparency and public trust. The MPSC is particularly interested in having Committee members publish articles about work related to the MPSC.

The MPSC also strongly encourages the OPTN to streamline deceased organ donor assessments, as recommended within the NASEM report. Similar to OPO allocation practices for hard-to-place organs, OPO donor evaluation practices vary significantly and the system can benefit from increased efficiencies and transparency gained through standardization. Standardizing the evaluation process will not only help identify any potential safety issues and help programs evaluate organ offers faster, but will also help standardize and streamline communication of updated donor information post-procurement, which the MPSC has repeatedly identified as a needed improvement within the donation and transplant system.

Additional information about the MPSC's goal to embed quality and increase transparency can be found throughout the rest of this report, including information about a national organ offer collaborative, referrals for policy improvements, and information-sharing with members.

U.S. Senate Committee on Finance Report

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

Impact of Disclosure of Peer Reviewed Information

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

opportunity but were uncertain about the impact that the disclosure of MPSC information may have on the MPSC's ability to recruit future members.

Considering Alternative Review Frameworks

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

In discussing alternative frameworks, the MPSC discussed at length the Committee's role and purpose. As noted in the Committee's proposal "Appendix L Revisions"⁴ in 2018, some of the MPSC's primary objectives are to "address potentially urgent and severe risks to patient health and public safety in a timely manner" and to "promote positive MPSC and member interactions focused on quality improvement." Similarly, in the Committee's enhancing Transplant Program Performance Metrics proposal, the Committee stated, "... the MPSC acknowledged it has a fiduciary responsibility to monitor member performance to identify potential patient safety issues. At the same time, the MPSC strives to support and collaborate with transplant programs to address performance improvement opportunities."⁵ The MPSC's charter also notes that the MPSC' "reviews events identified as presenting a risk to patient safety, public health or the integrity of the OPTN", and "evaluates and supports OPTN members by providing feedback on recommendations to improve members' performance, compliance and quality systems."⁶ In short, these are charges, responsibilities and improvement strategies all focused on best serving patients.

As part of this larger conversation, the MPSC shared its belief that it is important to differentiate between compliance and quality improvement. All compliance is quality improvement, but not all quality improvement is compliance. Within the OPTN, the MPSC is responsible for overseeing member compliance with OPTN policies and obligations. When an occurrence of noncompliance is identified, the

⁴ Briefing to the OPTN Board of Directors on Appendix L Revisions, June 2018. https://optn.transplant.hrsa.gov/media/2527/mpsc_boardreport_201806.pdf

⁵ Briefing to the OPTN Board of Directors on Enhance Transplant Program Performance Monitoring System, December 2021. https://optn.transplant.hrsa.gov/media/yctffgt2/20211206-bp-mpsc-enhnc-tx-prgrm-prfrmnc-mntrng-syst.pdf

⁶ https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/

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

Review MPSC Case Management Processes

To address specific concerns in the hearing report that many investigations were not forwarded to the MPSC for review, the MPSC recently implemented certain improvements.

Annual Review of MPSC Operational Rules

The MPSC uses operational rules to manage the Committee's workload and provide guidance to staff on how to process certain issues consistently. For example, rather than asking all Committee members to review every case, the MPSC determined that staff should assign cases to an ad hoc subcommittee of reviewers, and then assign cases to consent or discussion agendas for full Committee review, based on the ad hoc subcommittee's recommendations. Other operational rules may advise staff to close certain reviews with no action and only forward to the MPSC if a second event occurs, or to automatically place cases meeting certain criteria on a consent agenda with a specific and consistent recommended action, rather than posting it for an ad hoc subcommittee. The MPSC has already implemented this change and reviewed all operational rules at its October 2022 meeting. The MPSC will consider new rules as needed and will review and re-approve all rules on a yearly basis, likely at each October meeting. Beginning with the July 2023 cohort, new committee members will receive information about operational rules during new committee member orientation. The ongoing review of operational rules makes it possible to consistently improve the MPSC's process and the impact on patients.

Routine Review of All Investigative Activity

Second, the MPSC established a new process to review all investigative activity. Previously, the MPSC reviewed reports when investigations revealed a potential noncompliance with OPTN obligations. Though staff would consult with MPSC members during the investigation, particularly for guidance on clinical matters pertaining to medical judgement and patient safety, the full Committee did not receive information about investigative activity that were not identified as a potential noncompliance or safety issue. This process has been augmented to provide the MPSC with greater information and to aid in its decision making and oversight function. Now, the MPSC will regularly receive information including but not limited to:

• The number of reports submitted

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

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

Project to Require Additional Reporting of Specific Safety Events

The MPSC discussed whether the full Committee should receive additional updates on certain investigations more quickly, or perhaps even immediately, to ensure that potential issues are escalated in a timely fashion and to increase the involvement of the MPSC in investigative activities. The MPSC reviewed the existing criteria staff use to identify which types of reports require notification to Committee leadership and HRSA ex-officio members, and the timeline for escalation⁷ and determined that the current process works as intended. Notifying and obtaining feedback from MPSC and HRSA representatives while an investigation is ongoing proved to be an effective approach. The MPSC did not feel staff needed to escalate reports to the full Committee prior to the conclusion of the investigation.

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

⁷ Wakefield, Mary K., Administrator, Department of Health and Human Services; Letter to Jack Lake, M.D., President, Organ Procurement and Transplantation Network, August 5, 2011.

Increasing MPSC Involvement in Monitoring Decisions and Activities

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

Increasing Transparency

The MPSC fully supports efforts to increase transparency about MPSC reviews and share lessons learned. As described in the Educational Efforts section below, the MPSC has worked to develop a number of resources this year and continues to develop new offerings. In addition to its educational initiatives, the MPSC recently implemented a process change to refer suggestions for policy improvements to the POC based on MPSC case reviews.

Traditionally, when the MPSC has identified a potential need for policy changes based on its monitoring activities, the Committee has shared feedback directly with the leadership of the OPTN policy-making committee most likely to sponsor a project to revise or create a policy. Going forward, the MPSC will issue suggestions for policy projects through the POC. This will allow MPSC representatives to share the issue more broadly across the OPTN. It will also help ensure that the POC can prioritize and allocate resources for work on projects as needed and will centralize tracking of MPSC referrals with other project ideas. Ideas recently submitted to the POC using this process include:

- Policy 15.1 requires each OPO and transplant program to identify a patient safety contact who is available to receive and communicate information. Increased organ sharing has resulted in a large number of organizations working more closely together than ever before, yet there is widespread variability in practices pertaining to reporting, processing, and following-up on information with members' designated patient safety contacts. The MPSC recommends the OPTN standardize required processes for reporting this information.
- Consider guidance to help standardize protocols for allocation of hard-to-place organs, especially for hard-to-place kidneys. As discussed later in the Allocations Subcommittee section, OPOs are creating individual protocols to try and allocate hard-to-place organs with little CIT. Creating a framework to standardize these practices across the system is important for the integrity of the system, to increase efficiencies of allocation reviews, and has the potential to help allocate more organs for transplant.
- Consider clarifying DCD policies and the potential conflicts of interest for any individuals who
 may be employed by both the OPO and the donor hospital, as it is becoming increasingly
 common for OPOs to employ Intensivists who may care for patients who are later referred for
 donation.

- Consider centralized reporting of stored vessels to the OPTN, to help programs locate vessels for use when needed and to improve tracking of vessel disposition.
- Re-evaluate policy requirements for prohibited vessel storage, including whether HCV+ vessels should continue to be prohibited given the increased utilization of HCV+ organs, what empirical evidence exists to justify the requirement that vessels are discarded after 14 days, and at what time vessel storage is determined to begin.
- Re-consider policy that permits transplant programs to simultaneously accept two organ offers for the same candidate. The MPSC recognizes the challenges OPOs experience trying to reallocate an organ when programs turn down it down after accepting another organ.

Educational Efforts

Educating the transplant community is a continued priority of the MPSC. The MPSC currently has two groups working on educational projects. Additionally, staff and the MPSC work together to share a number of 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.

Patient Safety Education Work Group

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. This year, the MPSC formed a Patient Safety Work Group to analyze certain safety events to identify lessons learned and information that should be shared with the community. The work group collaborated with staff to create a presentation for this year's Transplant Quality Institute⁸ that described 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 MPSC recommendations for improvements to avoid similar issues. Key findings shared during the presentation include the following:

- When a transplant program is simultaneously managing multiple kidney offers, the organ itself, accompanying paperwork, or lids of packages containing the kidney can accidentally be switched, resulting in errors during the verification process.
- Consistency in verification and other operating room procedures is important. Slight variation in routine processes can lead to errors.

Feedback from the conference attendees indicated the content and level of information shared was helpful to members. The work group will continue to work with staff to identify information about other safety events that can be shared with the community to help drive continuous improvement and ensure patient safety.

Living Donor Event Work Group

The Living Donor Event project aims to share information with the transplant community on the incidence of living donor events and the lessons learned from MPSC reviews to promote effective

⁸ Womble, E., Lagana, K. (2022, October 20). *OPTN Patient Safety Data* [Conference presentation]. Transplant Quality Institute, Atlanta, GA, United States.

practices. The work group, composed of previous and current MPSC members, is initially focusing on living kidney donor deaths within two years of donation. The work group reviewed cases and categorized the nature of living donor deaths, particularly those that may have a potential to be donation-related, including complications during the recovery procedure, donor medical issues, suicide or potential suicide, and overdose. Currently, staff are combining summaries drafted by work group members into an article to be reviewed and edited. In addition, this topic has been submitted as a potential presentation at the next Transplant Management Forum.

Posters and Presentations

At its most recent meeting, the Committee expressed strong support for creating an annual report of MPSC activities that could be published so that the community is aware of aggregate data on Committee work.

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

IT System Enhancements

In response to MPSC review of cases, the Committee requested enhancements to the OPTN IT system to allow members to enhance their patient safety verification processes and alert programs to high-risk situations that require extra due diligence. As a result, the match results page now displays a hospital's unique identifier for each candidate, and now displays a warning message for each candidate on the match run who shares the same first and last name as another candidate at the same program.

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. The new monitoring system involves four risk-adjusted measures related to the patient journey: 90-day graft survival hazard ratio, 1-year conditional on 90-day graft survival hazard ratio, the offer acceptance rate ratio, and the pre-transplant mortality rate ratio.

The project has a phased implementation. In July 2022, the MPSC implemented the two post-transplant graft survival metrics. The MPSC will implement the organ offer acceptance rate ratio in July 2023, and the pre-transplant mortality rate ratio in July 2024⁹. The implementation and evaluation phase of the project includes developing education and resources for members and evaluation of post-implementation data. Earlier this year, the MPSC launched a <u>toolkit</u>¹⁰ on the OPTN website with information about the new monitoring system, the implementation timeline, risk-adjustment, and

⁹ https://optn.transplant.hrsa.gov/media/hgkksfuu/phase-1_tx-prgm-performance-monitoring_dec-2021.pdf

 $^{^{10}\,}https://optn.transplant.hrsa.gov/policies-bylaws/enhance-transplant-program-performance-monitoring/$

numerous educational resources. The MPSC will continue to update the toolkit, especially as new tools are available for the offer acceptance and pre-transplant mortality rate ratios.

To evaluate the impact of the new monitoring system, the Committee proposes to statistically examine approximately 125 different primary outcomes. Analysis of each metric is broken down into subgroups based on variables intended to capture risk-influencing patient or donor features, as well as key indicators of socioeconomic status and equity groups. Evaluation of the metrics will focus on trends in: deceased donor utilization rates, rates of new waitlist additions, offer acceptance rates, pre-transplant mortality rates, and post-transplant mortality rates. The MPSC will also evaluate the number of programs identified for review and qualitative insights from individual program interactions.

During the MPSC's most recent meeting in October 2022, the MPSC reviewed the evaluation plan and noted that with only three months since implementation it is still too early to review statistical testing results. The MPSC discussed the rates of new waitlist additions and observed there were no concerning decreases at this point. Tables 1 and 2 show the number of adult and pediatric programs identified for review under the recently implemented post-transplant metrics, and the number of programs that would have been identified for the pre-transplant metrics, if those metrics had been implemented.

	Implemented Post-Transplant Metrics		Not Yet Imple Transplar	Total	
	90 day graft survival	1 year conditional graft survival	Offer acceptance rate ratio	Pre-transplant mortality rate ratio	
Heart	7	5	5	3	13
Kidney	12	5	13	1	19
Liver	4	0	7	2	9
Lung	6	1	1	2	4
Pancreas	0	0	1	0	1
Total	29	11	27	8	75

Table 1: Number of Adult Programs Identified for New Performance Metrics in the July 2022 PSR

Table 2: Number of Pediatric Programs Identified for New Performance Metrics in the July 2022 PSR

	Implemented Post-Transplant Metrics		Not Yet Imple Transplar	Total	
	90 day graft survival	1 year conditional graft survival	Offer acceptance rate ratio	Pre-transplant mortality rate ratio	
Heart	2	2	2	4	10
Kidney	2	0	4	1	7
Liver	4	1	1	2	8
Lung	1	0	1	0	2
Pancreas	0	0	0	0	0
Total	9	3	8	7	27

The number of programs identified for post-transplant reviews decreased substantially, as expected. As previously noted, a criticism of the previous performance monitoring system was that fear of being identified for review dis-incentivized transplant programs' utilization of marginal and high-risk organs. The MPSC set new boundaries in a way to identify transplant programs that are clinically meaningful outliers and that may present a risk to patient health and public safety. The January 2022 Program-Specific Reports (PSR) identified 96 programs for review of either one-year patient or graft survival under the old performance monitoring system, compared to the 52 total programs identified under the new metrics in the July 2022 PSR. The MPSC will identify additional programs for review as the new pre-transplant metrics are implemented.

Offer Acceptance Collaborative

To support the MPSC's implementation of the offer acceptance rate ratio metric in July 2023, a collaborative is being developed to share effective offer acceptance practices and help transplant programs utilize improvement activities to increase their offer acceptance rates. This effort offers an opportunity to provide quality improvement coaching and support to interested members as well as engage with the MPSC throughout the process. The collaborative will launch in early 2023 and will last approximately six months. Though many aspects of the project will only be accessible to programs enrolled in the collaborative, the MPSC and staff plan to make offer acceptance tools and resources available for the entire donation and transplant community during and after the collaborative.

Allocations Subcommittee

This year, the MPSC observed a significant increase in the number of allocations out of sequence identified for MPSC review.

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

The MPSC reviewed each case using processes described in the Monitoring section later in this report. 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 CIT, late declines by accepting transplant programs, and logistical challenges such as the timing of that day's last commercial flight out of the local airport.

The MPSC formed a subcommittee to further analyze data, particularly to evaluate whether any patterns or trends of these allocations out of sequence suggest OPOs were inappropriately prioritizing transplant hospitals within a close proximity to the OPO's donation service area. It is important to note the MPSC's work so far has not revealed any evidence of such activity. Most often, OPOs seem to allocate hard-to-place organs out of sequence to transplant programs with high utilization of similar organs. As noted in the NASEM Report section above, the MPSC is concerned that one unintended consequence of allocations out of sequence, which seem appropriate to increase utilization of organs,

may be to create the perception of greater inequities in access to transplantation. The MPSC is also concerned that, as OPOs develop their own protocols and allocate to 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.

Until such a framework exists within OPTN policies, the MPSC expects the number of allocations out of sequence it reviews to continue to increase. The MPSC is concerned about the MPSC's workload and the sustainability of the current process. The subcommittee continues to evaluate how to prioritize reviews to focus on the issues of greatest potential concern, and how the MPSC can improve its review processes to identify and assess those scenarios. The Committee plans to develop a process to further evaluate the impact of transplant programs' declines after acceptances, which may result in allocations out of sequence, and agreed to focus its initial review on kidney acceptances. The MPSC anticipates that it may need to discuss increased data collection for allocation activities to ensure the MPSC can appropriately review them. The Committee also plans to review Scientific Registry of Transplant Recipients (SRTR) data and risk adjustment on hard-to-place organs and consider whether to utilize some aspect of those criteria to indicate which allocation cases may not need to be reviewed by the MPSC.

Monitoring Activities

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

As required by the OPTN contract, the MPSC receives the 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.

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 two pre-transplant metrics, offer acceptance rate ratio and pre-transplant waitlist mortality rate ratio, will be implemented in July 2023 and July 2024, respectively.

Table 4 below shows the total number of submissions reviewed by the MPSC from December 2021 – November 2022; 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 three review cycles. The newly identified programs for the year are included in the "send initial inquiry" category.

MPSC Action		Total				
	Heart	Kidney	Liver	Lung	Pancreas	TOLAI
Send initial inquiry	23	29	12	10	4	78
Continue to monitor	11	18	8	6	0	43
Skip a cycle	1	1	0	0	0	2
Informal discussions (held)	2	0	0	0	0	2
Informal discussions (offer pending)	1	0	0	1	0	2
Peer visit	0	1	0	0	0	1
Request to inactivate	0	0	0	0	0	0
Released	13	21	18	10	2	64

Table 4: Number of Transplant Program Outcome Submissions Reviewed

Functional Inactivity

As required by the OPTN Bylaws, Appendix L, Section D.10.C, the MPSC periodically reviews transplant program functional inactivity. Table 5 outlines the triggers for functional inactivity review if the program does not perform a transplant during the stated period:

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

Table 5: Transplant Program Functional Inactivity Requirements

Table 6 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.

MPSC Action	•					
IVIPSC ACTION	Heart	Kidney	Liver	Lung	Pancreas	Total
Send initial inquiry	2	1	1	1	0	5
Continue to monitor	1	0	0	1	0	2
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
Peer visit	0	0	0	0	0	0
Request to inactivate	0	0	0	0	0	0
Released	2	1	1	0	0	4

Table 6: Number of Transplant Program Functional Inactivity Submissions Reviewed

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

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

Tuble 7. Humber of of o ofgan field submissions herewed							
MPSC Action	Heart	Kidney	Liver	Lung	Pancreas	Aggregate	Total
Send initial inquiry	0	0	0	0	0	0	0
Continue to monitor	0	3	4	0	0	1	8
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	1	0	0	2	3

Table 7: Number of OPO Organ	Yield Submissions Reviewed

Compliance Reviews

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

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

Allocation Reviews

Staff review the match run for every allocation that results in a transplant to ensure an appropriate candidate received the organ. The MPSC reviews each transplant program and OPO member's allocation issues on a yearly basis in order to identify and evaluate potential trends or behaviors. As noted in the Allocation Subcommittee section above, the MPSC has noted a significant increase in the number of OPO allocations out of sequence in the past year, and the Committee has formed a work group to evaluate potential changes and improvements to the MPSC's review of allocations information to identify the most concerning patterns or trends.

Table 8 below notes 60 total allocation reviews for the year. These figures include one annual review for any OPO with identified deviations. 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. Of the seven instances where the MPSC issued a Notice of Noncompliance, two were issued to OPOs allocating out of sequence. In both cases, the MPSC was concerned that the OPOs bypassed candidates on the kidney waitlist prior to cross-clamp. Though the MPSC acknowledged the OPOs were making good faith attempts to allocate kidneys that were likely difficult to place, the MPSC was concerned that the OPO made no attempts to place the kidneys according to the match run. As previously noted, the MPSC believes the OPTN should standardize practices for allocation of hard-to-place organs to minimize the risk associated with varied OPO practices.

The MPSC issued the five remaining Notices of Noncompliance to transplant programs that transplanted a candidate other than the candidate for whom they originally accepted the organ. In most of these instances, the MPSC determined that the program made decisions to avoid non-utilization of an organ once the intended recipient was deemed not suitable but failed to properly notify the OPO of the alternative allocation.

Site Surveys

Staff survey each transplant program and OPO approximately once every three years. If staff identify any noncompliances during the review, they apply a survey evaluation tool to determine whether to conduct a virtual follow up review of the applicable policies in approximately nine months. If the

member appropriately addressed any areas of noncompliance on a follow up review, the review is closed with no action. If the member does not demonstrate improvement on the follow up survey, staff will forward the survey findings to the MPSC for review. The MPSC typically requests an additional follow up review and may issue a Notice of Noncompliance for continued failure to improve.

Table 8 below shows the number of total surveys conducted 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.

Investigations

Staff receive reports directly through the Safety Situation and Living Donor Event sections of the OPTN Patient Safety Reporting Portal, as well as through the Member Reporting Line, fax, mail, and referrals from other staff, including Patient Services. From December 1, 2021 to October 31, 2022, staff received 497 reports.

Investigative staff triage each report to assess the potential risk to patient safety or public health and determine if immediate intervention is needed. Staff escalate reports of certain events to MPSC leadership and HRSA according to established criteria. Staff investigate reports by sending inquiries and requests for information to involved parties 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. If the investigation substantiates a noncompliance, staff forward the investigation results to the MPSC for review. If the investigation is unable to substantiate the report and/or determines no violation occurred, staff have historically closed the case and have not forwarded it to the MPSC for review.

As described in the U.S. Senate Committee on Finance Report section above, the MPSC recently implemented a new process to review information associated with all investigations.

MPSC Action	Allocation Reviews	Site Surveys	Investigations				
Close with no action	53	29	73				
Follow up survey	n/a	9	n/a				
Notice of Noncompliance	7	0	78				
Letter of Warning	0	0	3				
Probation	0	0	0				
Member Not in Good Standing	0	0	1				
Informal Discussions (held)	0	0	4				
Informal Discussions (offer							
pending)	0	0	1				
Interviews (held)	0	0	2				
Interviews (offer pending)	0	0	0				
Peer Visit	0	0	3				

Table 8: Compliance Reviews and MPSC Actions

Membership Applications

The MPSC monitors compliance with OPTN membership requirements, including new member applications. Table 9 below summaries the different types of applications reviewed this year. The total number of applications reviewed increased from 542 last year to 619. The increase is due in large part to the rise in the number of transplant program key personnel applications for primary physicians and primary surgeons, which increased from 317 in the 2021 report to 418. The MPSC utilizes an operational rule that places key personnel applications on to a consent agenda for MPSC review and approval, if staff determine the applicant fulfills the applicable Bylaw requirements. As a result, the increase in key personnel applications required additional staff resources but did not significantly impact the MPSC's workload.

Type of Application	Number
Transplant Hospitals and Programs	
New Transplant Hospital	1
New Programs and Components	17
Key Personnel Applications	418
Program and Component Conditional Approvals	10
Conditional to Full Approval	10
Conditional Extension	3
Program and Component Long Term Inactivations	31
Inactivation Extensions	5
Program and Component Reactivations	13
Program and Component Withdrawals	12
Transplant Hospital Withdrawals	2
Organ Procurement Organizations (OPOs)	
OPO Key Personnel Change Notifications	20
Histocompatibility Labs	
New Histocompatibility Labs	1
Histocompatibility Lab Key Personnel Change	51
Histocompatibility Lab Withdrawal	1
Histocompatibility Lab Reactivation	0
Non-Institutional Members	
New Non-Institutional Members	7
Non-Institutional Membership Renewal	17
ΤΟΤΑΙ	619

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: MPSC-related Posters and Presentations

Title	Presenter(s)	Type of Presentation	Conference/Meeting	Description
Member Quality and MPSC Update	Member Quality Staff	Presentation	Summer 2022 Regional Meetings	Staff presented an update at all eleven Summer 2022 Regional Meetings about Site Survey, Individual Member Focused Improvement (IMFI), Collaborative Improvement, and the new MPSC Performance Metrics.
Metrics from the OPTN Perspective	Darren Stewart	Presentation	AST Kidney/Pancreas Transplant Medical Directors Forum	Staff gave a presentation about the new transplant program performance monitoring system including information about the number of kidney programs that would have met the new criteria, the MPSC interaction and performance improvement zones and resources available to transplant programs such as the individual member focused improvement initiative, OPTN data tools and kidney offer filters explorer.
A New Era of Transplant Program Evaluation Metrics: The MPSC Perspective	Steven R. Potter M.D., FACS	Presentation	Transplant Management Forum	An MPSC member collaborated with the SRTR's Jon Snyder to give a presentation on the purpose and goals of the new transplant program performance monitoring system, the new metrics, the implementation plan, the MPSC interaction and performance improvement zones and resources available to transplant programs.
Improving Patient Safety Together via the OPTN Improving Patient Safety Portal	Emily Womble	Poster	Transplant Management Forum	The poster was about the OPTN Improving Patient Safety Portal accessible via UNet and was meant to help inform the community about this vital tool for the community and the OPTN to partner on improving patient safety across the community.

The Individual Member Focused Improvement (IMFI) Project, The OPTN's Novel Approach to Quality	Amy Minkler	Poster	Transplant Management Forum	The poster presented an overview of the Individual Member Focused Improvement (IMFI) project, which is the Organ Procurement and Transplantation Network (OPTN)'s novel approach to customized performance improvement, and the first three pilot projects.
OPTN Peer Review: Member Quality and the OPTN Membership and Professional Standards Committee	Betsy Warnick and Katie Favaro	Presentation	UNOS Primer	Staff presented about Member Quality, the Membership and Professional Standards Committee (MPSC) structure, processes and activity, and MPSC performance review changes.
Site Survey	Jon Dyer and Brigid Burns	Presentation	UNOS Primer	Staff presented about what to expect in the lead up to and during a Site Survey for both a transplant hospital and an Organ Procurement Organization (OPO).
Individual Member Focused Improvement (IMFI)	Amanda Young	Presentation	UNOS Primer	This presentation was an overview of the Individual Member Focused Improvement (IMFI) project, which is the Organ Procurement and Transplantation Network (OPTN)'s novel approach to customized performance improvement, and what improvement activities can be offered to help members.
Encouraging Self- Reporting and Patient Safety Portal	Amanda Young	Presentation	UNOS Primer	This presentation was about the OPTN Improving Patient Safety Portal accessible via UNet and how the data collected via the portal will be used to improve the community. The goal is to encourage additional self- reporting by OPTN members to build a larger sample size of data.

Individual Member Focused Improvement Initiative and the OPTN Data Resources	Amanda Young	Poster	Transplant Quality Institute	The IMFI team presented a poster about the effectiveness of starting each of the pilot projects with hands on OPTN Data Portal tools training sessions. The poster presented data about whether the trainings increased regular utilization of the tools and what can be done differently in the future to improve the offering.
MPSC Performance Monitoring and Program Support	Zoe Stewart- Lewis, M.D.	Presentation	Transplant Quality Institute	The MPSC chair gave a presentation on the MPSC's purpose and goals for the new transplant program performance monitoring and the implementation plan, provided information about the four metrics and data on the number of programs that met the criteria for each metric, described the MPSC interaction and performance improvement zones and the review process for programs identified under the new criteria, and provided information on OPTN member improvement activities including the individual member focused improvement initiative, the upcoming offer acceptance collaborative and resources available to transplant programs
Sharing OPTN Patient Safety Event Data	Emily Womble and Kaylin Sheranek	Presentation	Transplant Quality Institute	Staff presented about the OPTN Improving Patient Safety Portal; they reviewed what it is, how it works and why it's important. Then there was a review of patient safety event data, including the most common patient safety events and errors, case examples, and what the MPSC wants the community to know about how to respond when patient safety events occur.

Appendix B: Monitoring Effectiveness Baseline Report

OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Contract:	HHSH250-2019-00001C
Task:	United Network for Organ Sharing
Item:	Organ transplantation
Due:	10 business days prior to each MPSC multi day meeting
Submitted:	October 12, 2022

Monitoring Effectiveness Baseline Report

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 deviation and fiscal quarter during which the deviation took place, July 1, 2020 – June 30, 2022

July 1, 2020	June 30, 20					
Fiscal year	Actual vs	Allocation out of	Local backup	Other	Clean	Total
& quarter	intended	sequence				
FY2020 Q4	1 (0.01)%	326 (3.71)%	82 (0.93)%	146 (1.66)%	8243 (93.69)%	8798
FY2021 Q1	0 (0)%	347 (4.03)%	154 (1.79)%	85 (0.99)%	8026 (93.2)%	8612
FY2021 Q2	2 (0.02)%	419 (4.8)%	126 (1.44)%	59 (0.68)%	8127 (93.06)%	8733
FY2021 Q3	11 (0.11)%	646 (6.64)%	7 (0.07)%	107 (1.1)%	8964 (92.08)%	9735
FY2021 Q4	5 (0.06)%	682 (7.74)%	9 (0.1)%	88 (1)%	8026 (91.1)%	8810
FY2022 Q1	0 (0)%	634 (7.43)%	7 (0.08)%	78 (0.91)%	7810 (91.57)%	8529
FY2022 Q2	2 (0.02)%	818 (9.29)%	3 (0.03)%	86 (0.98)%	7893 (89.67)%	8802
FY2022 Q3	0 (0)%	859 (9.33)%	47 (0.51)%	114 (1.24)%	8182 (88.92)%	9202

Table 1 shows the number of organ allocations resulting in a transplant that deviated from organ allocation policy between July 1, 2020 and June 30, 2022. Deviation types indicate how an allocation deviated from policy. Most deviations are allocations wherein an OPO chose to bypass a candidate on a match run ("Allocation Out of Sequence"). The "Other" category includes directed donations, allocations where the recipient was not on the match run, and any other type of deviation from organ allocation policy. The data show a consistent increase over time in the proportion of allocations that are out of sequence.

		Was the case sent to the	MPSC?
Timeframe	MPSC Meeting	Yes	No
07/29/2020 - 11/24/2020	February 2021	23 (22.12%)	81 (77.88%)
11/25/2020 - 04/20/2021	July 2021	32 (20.65%)	123 (79.35%)
04/21/2021 - 07/27/2021	October 2021	32 (21.62%)	116 (78.38%)
07/28/2021 - 11/24/2021	February 2022	31 (22.79%)	105 (77.21%)
11/25/2021 - 04/29/2022	July 2022	40 (19.51%)	165 (80.49%)

Table 2. Quantity of cases processed by Patient Safety analysts, subset by whether the case was sent to the MPSC, July 29. 2020 - April 29. 2022

Table 2 displays the number of cases reviewed by Incident Handling patient safety analysts that were or were not sent to the MPSC between July 29, 2020 - April 29, 2022. Data is subset by the timeframe within which analysts received each case, and these timeframes are ranges of dates wherein most cases received within the range and sent to the MPSC would have been reviewed during the corresponding MPSC meeting. July 29, 2020 and April 29, 2022 are used as start and end dates so that their associated MPSC meeting dates closely align as possible with the July 1, 2020 and June 30, 2022 timeframe that Tables 1 & 3, 4 and 7 use. While the proportions of cases reviewed that are sent to the MPSC are not consistent over all timeframes, typically about one fifth of cases reviewed by Incident Handling patient safety analysts were sent to the MPSC during each timeframe.

Table 3. Proportion of member touchpoint survey respondents who answered "Agree" or "Strongly Agree" when asked to answer whether they Strongly Disagreed, Disagreed, Agreed or Strongly Agreed with the following statement about their touchpoint: "The process helped us identify areas of improvement.", July 1, 2020 – June 30, 2022

Fiscal year & quarter	Respondent's answer					
	Agree or strongly agree	Disagree or strongly disagree				
FY2020 Q4	20 (100%)	0 (0%)				
FY2021 Q1	17 (94.4%)	1 (5.6%)				
FY2021 Q2	19 (100%)	0 (0%)				
FY2021 Q3	21 (95.5%)	1 (4.5%)				
FY2021 Q4	21 (100%)	0 (0%)				
FY2022 Q1	15 (93.8%)	1 (6.3%)				
FY2022 Q2	17 (94.4%)	1 (5.6%)				
FY2022 Q3	15 (100%)	0 (0%)				

Table 3 indicates the distribution of responses that UNOS touchpoint survey respondents provided when asked whether they strongly agreed, agreed, disagreed, or strongly disagreed with the following statement about their touchpoint: "The process helped us identify areas of improvement." This includes the following touchpoints that occurred between July 1, 2020 and June 30, 2022: site survey, informal discussion, interview, hearing, and peer visit. The overwhelming majority of survey recipients answer that they agree or strongly agree with that statement.

Member type	Organ	Policy	Туре	N Total records/	Were records/ele compliant?	ements
				elements	Yes	No
Transplant HR Recipient		6.1	Records	1460	1446 (99.04%)	14 (0.96%)
Recipient		6.1/6.2/6.3/6.4 DEE	Records			
			Records			
-		6.4	Records	471	470 (99.79%)	
	KI	3.6.C	Records	45	31 (68.89%)	14 (31.11%)
		5.3.C	Records	636	603 (94.81%)	33 (5.19%)
		8.4	Records	2696	2633 (97.66%)	63 (2.34%)
		8.5.A	Records	1025		
			Records	records/ elements compliant? Yes No secords 1460 1446 (99.04%) 14 (0.9 (0.23) secords 2379 2271 (95.46%) 108 (4. (0.23) secords 441 440 (99.77%) 1 (0.23) secords 471 470 (99.79%) 1 (0.24) secords 636 603 (94.81%) 33 (5.1) secords 2696 2633 (97.66%) 63 (2.3) secords 1025 1013 (98.83%) 12 (1.1) secords 1025 1013 (98.83%) 12 (1.2) secords 10824 10788 (99.67%) 36 (0.3) secords 10824 10514 (97.14%) 310 (2) secords 10824 10514 (97.14%) 310 (2) secords 10824 10514 (97.14%) 310 (2) secords 2067 2034 (98.4%) 33 (1.6) secords 10824 10514 (97.14%) 310 (2) secords 10824 1016 (86.24%) 178 (1) secords 1088 1031 (94.76%)		
		 6.1/6.2/6.3/6.4 DEE 6.2 6.4 3.6.C 5.3.C 8.4 8.5.A 8.5.D 8.5.F 8.5.G 16.6.B Destroying 16.6.C Reporting 9 9.1.A/9.1.B/9.1.C/9.2 9.6/9.2 9.9.B 10.1 DEE (listings) 10.1 Listings 10.1.A/10.1.B/10.1.C (LU, peds) (Listings) 11.4.B 15.2 15.3.B 15.3.C 3.2 3.5 (NOL) 3.5 (NOR) 3.9 5.8.B 15.4.A 16.5 18.1 (PTRs) 18.1 (Timeliness DDRs) 18.1 (accuracy Accuracy DDRs) 18.1 (Accuracy Accuracy Ac	Records			
			Records			
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					rds/ compliant? ents Yes No 1446 (99.04%) 14 (0 2271 (95.46%) 108 (440 (99.77%) 1 (0. 470 (99.79%) 1 (0. 31 (68.89%) 14 (3 603 (94.81%) 33 (5 2633 (97.66%) 63 (2 1013 (98.83%) 12 (1 87 (97.75%) 2 (2. 291 (91.22%) 28 (8 79 (100%) 0 (09 4 10788 (99.67%) 36 (0 4 10514 (97.14%) 310 (2351 (95.11%) 121 (348 (98.03%) 7 (1. 2034 (98.4%) 33 (1 487 (96.82%) 16 (3 1031 (94.76%) 57 (5 1116 (86.24%) 178 (32 (100%) 0 (09 4 1018 (96.4%) 38 (3 498 (69.75%) 216 (3 1031 (94.76%) 57 (5 1116 (86.24%) 178 (32 (100%) 0 (09 4 1018 (96.4%) 38 (3 498 (69.75%) 216 (1 1732 (96.38%) 65 (3 439 (73.53%) 158 (1 4099 (98.84%) 48 (1 3166 (96.35%) 120 (1 652 (97.02%) 20 (2 5001 (99.44%) 28 (0 5592 (91.21%) 539 (1 662 (98.81%) 8 (1. 665 (99.25%) 5 (0. 7 64984 (99.73%) 173 (1 14636 (99.49%) 75 (0 3 15104 (99.22%) 119 (1 167 (75.91%) 53 (2 165 (76.39%) 51 (2 496 (100%) 0 (09 218 (100%) 0 (09 218 (100%) 0 (09 218 (100%) 0 (09 218 (100%) 0 (09 63 (100%) 0 (09 63 (100%) 0 (09 641 (98.66%) 9 (1. 656 (97.91%) 14 (2 626 (93.43%) 44 (6 675 (96.43%) 25 (3)	
			Records			
						No 9.04%) 14 (0.96%) 5.46%) 108 (4.54%) .77%) 1 (0.23%) .79%) 1 (0.21%) 39%) 14 (31.11%) .81%) 33 (5.19%) .766%) 63 (2.34%) 8.83%) 12 (1.17%) 75%) 2 (2.25%) .22%) 28 (8.78%) %) 0 (0%) 99.67%) 36 (0.33%) 97.14%) 310 (2.86%) 5.11%) 121 (4.89%) .03%) 7 (1.97%) 8.4%) 33 (1.6%) 8.2%) 16 (3.18%) 4.76%) 57 (5.24%) 6.24%) 178 (13.76% %) 0 (0%) 6.38%) 65 (3.62%) .53%) 158 (26.47% 8.84%) 48 (1.16%) 6.35%) 120 (3.65%) .02%) 20 (2.98%) 9.44%) 28 (0.56%) .25%) 5 (0.75%) 99.73%) 173 (0.27%) 99.44%)
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	LU				. ,	
		-				
			Records	32	32 (100%)	0 (0%)
	PA		Records	1056	1018 (96.4%)	38 (3.6%)
	Non- specified	15.2	Records			
			Records	1797		
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		2.11.E #5 & #6 [PA]	Records			
		2.11.E #5 & #6 [PA] 2.13 #5	Records	670	670 (100%)	0 (0%)
		2.11.E #5 & #6 [PA] 2.13 #5 2.14.B	Records Records	670 670	670 (100%) 661 (98.66%)	0 (0%) 9 (1.34%)
		2.11.E #5 & #6 [PA] 2.13 #5 2.14.B 2.14.C #6	Records Records Records	670 670 670	670 (100%) 661 (98.66%) 656 (97.91%)	0 (0%) 9 (1.34%) 14 (2.09%)
		2.11.E #5 & #6 [PA] 2.13 #5 2.14.B 2.14.C #6 2.2 #14	Records Records Records Records	670 670 670 670	670 (100%) 661 (98.66%) 656 (97.91%) 626 (93.43%)	0 (0%) 9 (1.34%) 14 (2.09%) 44 (6.57%)
		2.11.E #5 & #6 [PA] 2.13 #5 2.14.B 2.14.C #6	Records Records Records	670 670 670	670 (100%) 661 (98.66%) 656 (97.91%) 626 (93.43%) 675 (96.43%)	0 (0%) 9 (1.34%) 14 (2.09%) 44 (6.57%) 25 (3.57%)

Table 4. Transplant recipient program, living donor program, and organ procurement organization policy compliance rates, subset by policy and associated organ type, July 1, 2020 – June 30, 2022*

		2.2 #5	Records	670	670 (100%)	0 (0%)
		2.3	Records	650	650 (100%)	0 (0%)
		2.4	Records	670	670 (100%)	0 (0%)
		2.5	Records	685	679 (99.12%)	6 (0.88%)
		2.6.B	Records	147	146 (99.32%)	1 (0.68%)
		2.8 #7	Records	663	653 (98.49%)	10 (1.51%)
		2.9 #1	Records	660	658 (99.7%)	2 (0.3%)
		2.9 #2	Records	661	659 (99.7%)	2 (0.3%)
		2.9 #3**	Records	139	139 (100%)	0 (0%)
		Accuracy of DonorNet	Elements	4750	4724 (99.45%)	26 (0.55%)
		Accuracy of Serologies	Records	670	661 (98.66%)	9 (1.34%)
Living	LDK	13.4.A (LDK)	Records	80	64 (80%)	16 (20%)
Donor		13.4.C (LDK)	Elements	1344	1176 (87.5%)	168 (12.5%)
		14.4.B	Elements	6952	6933 (99.73%)	19 (0.27%)
		18.5.A (Accuracy) KI 6	Elements	3780	3628 (95.98%)	152 (4.02%)
		months				
		18.5.A (Accuracy) KI one year	Elements	1027	1001 (97.47%)	26 (2.53%)
	LDL	14.4.B	Elements	12	12 (100%)	0 (0%)
		14.4.C	Elements	966	966 (100%)	0 (0%)
		18.5.B (Accuracy) LI 6 months	Elements	1152	1122 (97.4%)	30 (2.6%)
		18.5.B (Accuracy) LI one year	Elements	338	331 (97.93%)	7 (2.07%)
	Non-	14.1.A	Elements	11193	10738 (95.93%)	455 (4.07%)
	specified	14.2.A	Elements	3656	3321 (90.84%)	335 (9.16%)
		14.3	Elements	38336	36738 (95.83%)	1598 (4.17%)
		14.4.A	Elements	26090	25913 (99.32%)	177 (0.68%)
		14.5.A/14.5.B	Elements	1612	1608 (99.75%)	4 (0.25%)
		14.5.C	Elements	808	807 (99.88%)	1 (0.12%)
		14.7	Records	967	873 (90.28%)	94 (9.72%)
		14.8.B	Records	137	99 (72.26%)	38 (27.74%)
		18.1 (Accuracy)	Elements	14623	14268 (97.57%)	355 (2.43%)
		18.1 (Timely)	Records	815	723 (88.71%)	92 (11.29%)

* Aggregate audit data is available several months after audits are performed, and data from some audits between March 31, 2022 – June 30, 2022 are not yet available, so the quarter is not included in order to not misrepresent quarter totals
 ** Policy 2.9 #3 was retired on 3/1/21

Table 4 shows the quantity of the records or elements of transplant programs, living donor programs, and organ procurement organizations reviewed by site surveyors, by policy and whether the surveyor identified a record as being compliant with policy. This includes records that were surveyed between July 1, 2020 and June 30, 2022. Highlighted are policies with a greater than 5 percent non-compliance rate. Targeted education and monitoring changes, as well as system enhancements have been made to help increase compliance with low compliance policies. Some examples are described below:

OPTN Policy 3.6.C: Individual Waiting Time Transfers

We have seen a low rate of compliance with this policy so we are expanding 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 will be providing a greater service for our members.

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

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

OPTN Policy 8.5.F: Highly Sensitized Candidates

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

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

These policies were implemented in 2021 to align with the 2020 PHS Guidelines. We have 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 new policies as well as providing resources to members on the OPTN website.

OPTN Policies 13.4.A and 13.4.C

We have seen a lower rate of compliance with these policies, so we are expanding 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 are increasing 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 will retire our monitoring of these policies but for blood and urine cultures required by Policy 2.9,

Other improvements made based on educational referrals:

Members were having trouble tracking LAS >50 and policy requirements. There is now a waitlist report to aide members in complying with policy. Lung height and weight fields have been decoupled to help members enter accurate data. PA02 values now allow a decimal point to allow for more accurate data entry.

Table 5. Proportion of members which underwent a <u>routine site survey</u>, and based on those findings the MPSC or Member Quality either did or did not recommend that they participate in a focused desk review, July 1, 2020 – March 31, 2022*

Member type	Fiscal year/quarter	N Total programs	Did the MPSC or UNOS recommend for a			
		surveyed	focused desk rev	view?		
			Yes	No		
Transplant Recipient	FY2020 Q4	74	38 (51.35%)	36 (48.65%)		
	FY2021 Q1	62	38 (61.29%)	24 (38.71%)		
	FY2021 Q2	65	48 (73.85%)	17 (26.15%)		
	FY2021 Q3	86	67 (77.91%)	19 (22.09%)		
	FY2021 Q4	52	31 (59.62%)	21 (40.38%)		
	FY2022 Q1	46	25 (54.35%)	21 (45.65%)		
	FY2022 Q2	53	28 (52.83%)	25 (47.17%)		
ОРО	FY2020 Q4	surveyed focused desk review? Yes No 74 38 (51.35%) 36 (48.65%) 62 38 (61.29%) 24 (38.71%) 65 48 (73.85%) 17 (26.15%) 86 67 (77.91%) 19 (22.09%) 52 31 (59.62%) 21 (40.38%) 46 25 (54.35%) 21 (45.65%)	1 (14.29%)			
	FY2021 Q1	5	5 (100%)	0 (0%)		
	FY2021 Q2	2	2 (100%)	0 (0%)		
	FY2021 Q3	5	4 (80%)	1 (20%)		
	FY2021 Q4	4	3 (75%)	1 (25%)		
	FY2022 Q1	6	6 (100%)	0 (0%)		
	FY2022 Q2	6	6 (100%)	0 (0%)		
Living Donor	FY2020 Q4	27	16 (59.26%)	11 (40.74%)		
	FY2021 Q1	23	12 (52.17%)	11 (47.83%)		
	FY2021 Q2	22	12 (54.55%)	10 (45.45%)		
	FY2021 Q3	26	11 (42.31%)	15 (57.69%)		
	FY2021 Q4	21	15 (71.43%)	6 (28.57%)		
	FY2022 Q1	15	10 (66.67%)	5 (33.33%)		
	FY2022 Q2	18		8 (44.44%)		

* Aggregate audit data is available several months after audits are performed, and data from some audits between March 31, 2022 – June 30, 2022 are not yet available. In order to not misrepresent that guarter, it is not included in this table.

Table 5 indicates the number and proportion of transplant recipient routine site surveys which were performed between July 1, 2020 and March 31, 2022 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, between around 1 in 4 or 1 in 2 of transplant recipient and living donor program routine site surveys result in a recommendation for a focused desk review. OPO routine surveys typically do not result in a recommendation for a focused desk review.

Member type	Fiscal year/quarter	N Total programs surveyed		or UNOS recommend for an ed desk review?
			Yes	No
Transplant Recipient	FY2020 Q4	31	20 (64.52%)	11 (35.48%)
	FY2021 Q1	22	17 (77.27%)	5 (22.73%)
	FY2021 Q2	39	31 (79.49%)	8 (20.51%)
	FY2021 Q3	22	18 (81.82%)	4 (18.18%)
	FY2021 Q4	26	20 (76.92%)	6 (23.08%)
	FY2022 Q1	22	19 (86.36%)	3 (13.64%)
	FY2022 Q2	31	27 (87.1%)	4 (12.9%)
OPO	FY2020 Q4	0	0	0
	FY2021 Q1	2	2 (100%)	0 (0%)
	FY2021 Q2	1	1 (100%)	0 (0%)
	FY2021 Q3	1	1 (100%)	0 (0%)
	FY2021 Q4	0	0	0
	FY2022 Q1	0	0	0
	FY2022 Q2	1	1 (100%)	0 (0%)
Living Donor	FY2020 Q4	13	11 (84.62%)	2 (15.38%)
	FY2021 Q1	13	11 (84.62%)	2 (15.38%)
	FY2021 Q2	11	10 (90.91%)	1 (9.09%)
	FY2021 Q3	9	8 (88.89%)	1 (11.11%)
	FY2021 Q4	10	10 (100%)	0 (0%)
	FY2022 Q1	11	10 (90.91%)	1 (9.09%)
	FY2022 Q2	17	15 (88.24%)	2 (11.76%)

Table 6. Proportion of members which underwent a <u>focused desk review</u>, and based on those findings the MPSC or Member Quality either did or did not recommend that they participate in another focused desk review, July 1, 2020 – March 31, 2022*

* Aggregate audit data is available several months after audits are performed, and data from some audits between March 31, 2022 – June 30, 2022 are not yet available. In order to not misrepresent that quarter, it is not included in this table.

Table 6 shows the proportion of focused desk reviews between April 1, 2020 and March 31, 2022 which resulted in either the MPSC or Member Quality recommending an additional follow-up focused desk review. Each quarter around 1 in 5 or 1 in 6 transplant program focused desk reviews resulted in an MPSC or MQ recommendation for an additional focused desk review. There tend to be few OPO desk reviews, but since FY2020 Q3, only one has resulted in a recommendation for an additional desk. Typically each quarter around 1 in 8 living donor program desk reviews result in a recommendation for an additional desk review.

(OPTN)

Table 7. Proportion of transplant recipient programs participating in at least two routine site surveys between January 1, 2016 and June 30, 2022* that increased, decreased, or retained the same compliance rate from their 2nd-most-recent to their most-recent routine survey, by policy and whether the 2nd-most-recent survey resulted in a recommendation for a follow-up focused desk review

Member	Organ	Policy	Data	Yes desk revie	ew recommendat	ion cohort	No desk review	recommendatior	n cohort	Yes Inc. % - No
type	type		type	Decrease	Same	Increase	Decrease	Same	Increase	% - No Inc. %
Transplant	HR	6.1	Records	1 (2.94%)	25 (73.53%)	8 (23.53%)	6 (9.52%)	49 (77.78%)	8 (12.7%)	11
Recipient		6.1/6.2/6.3/6.4 DEE	Records	21 (51.22%)	6 (14.63%)	14 (34.15%)	34 (44.16%)	15 (19.48%)	28 (36.36%)	
		6.2	Records	1 (10%)	9 (90%)	0 (0%)	4 (15.38%)	21 (80.77%)	1 (3.85%)	
		6.4	Records	1 (9.09%)	10 (90.91%)	0 (0%)	0 (0%)	29 (100%)	0 (0%)	
	KI	3.6.C	Records	0 (0%)	1 (100%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	
		5.3.C	Records	3 (6.67%)	36 (80%)	6 (13.33%)	5 (8.62%)	51 (87.93%)	2 (3.45%)	10
		8.4	Records	38 (44.19%)	20 (23.26%)	28 (32.56%)	62 (50.41%)	54 (43.9%)	7 (5.69%)	27
		8.5.A	Records	3 (4.29%)	61 (87.14%)	6 (8.57%)	1 (0.91%)	104 (94.55%)	5 (4.55%)	
		8.5.D	Records	2 (13.33%)	13 (86.67%)	0 (0%)	3 (18.75%)	12 (75%)	1 (6.25%)	
		8.5.F	Records	11 (20.75%)	36 (67.92%)	6 (11.32%)	18 (23.68%)	47 (61.84%)	11 (14.47%)	
		8.5.G	Records	0 (0%)	3 (100%)	0 (0%)	0 (0%)	3 (100%)	0 (0%)	
	LI	16.6.B Destroying	Records	1 (6.67%)	10 (66.67%)	4 (26.67%)	7 (25%)	18 (64.29%)	3 (10.71%)	16
		16.6.C Reporting	Records	7 (46.67%)	1 (6.67%)	7 (46.67%)	16 (57.14%)	5 (17.86%)	7 (25%)	22
		9	Records	27 (51.92%)	3 (5.77%)	22 (42.31%)	44 (60.27%)	9 (12.33%)	20 (27.4%)	15
		9.1.A/9.1.B/9.1.C/9.2	Records	3 (7.32%)	32 (78.05%)	6 (14.63%)	2 (3.03%)	64 (96.97%)	0 (0%)	15
		9.6/9.2	Records	13 (25%)	25 (48.08%)	14 (26.92%)	19 (26.03%)	48 (65.75%)	6 (8.22%)	19
		9.9.B	Records	1 (10%)	5 (50%)	4 (40%)	0 (0%)	10 (100%)	0 (0%)	40
	LU	10.1 DEE (listings)	Records	0	0	0	1 (100%)	0 (0%)	0 (0%)	
		10.1 DEE (variables)	Records	5 (100%)	0 (0%)	0 (0%)	2 (22.22%)	1 (11.11%)	6 (66.67%)	
		10.1 Listings	Records	0	0	0	1 (100%)	0 (0%)	0 (0%)	
		10.1 Variables	Records	2 (28.57%)	0 (0%)	5 (71.43%)	5 (35.71%)	2 (14.29%)	7 (50%)	
		10.1.A/10.1.B/10.1.C	Records	0	0	0	0 (0%)	1 (100%)	0 (0%)	
		(LU, peds) (Listings)								
	Non-	15.3.B	Records	36 (18%)	122 (61%)	42 (21%)	46 (15.28%)	240 (79.73%)	15 (4.98%)	16
	specified	3.2	Records	12 (5.26%)	201 (88.16%)	15 (6.58%)	17 (4.58%)	340 (91.64%)	14 (3.77%)	
		3.5 (NOL)	Records	44 (19.38%)	143 (63%)	40 (17.62%)	65 (17.52%)	263 (70.89%)	43 (11.59%)	
		3.5 (NOR)	Records	43 (27.39%)	105 (66.88%)	9 (5.73%)	58 (21.97%)	194 (73.48%)	12 (4.55%)	
		3.9	Records	21 (9.42%)	191 (85.65%)	11 (4.93%)	42 (11.63%)	307 (85.04%)	12 (3.32%)	
		5.8.B	Records	69 (32.39%)	46 (21.6%)	98 (46.01%)	147 (41.76%)	187 (53.13%)	18 (5.11%)	41
OPO	OPO	15.4.A	Records	0 (0%)	1 (100%)	0 (0%)	1 (10%)	7 (70%)	2 (20%)	
		16.5	Records	0 (0%)	1 (100%)	0 (0%)	2 (20%)	8 (80%)	0 (0%)	

		18.1 (PTRs)	Records	0 (0%)	1 (100%)	0 (0%)	4 (40%)	3 (30%)	3 (30%)	
		18.1 (Timeliness DDRs)	Records	1 (100%)	0 (0%)	0 (0%)	4 (40%)	4 (40%)	2 (20%)	
		18.1 (Timeliness feedback)	Records	0 (0%)	0 (0%)	1 (100%)	3 (30%)	4 (40%)	3 (30%)	
		18.1 (noneligible)	Records	0	0	0	2 (28.57%)	3 (42.86%)	2 (28.57%)	
		2.11.B #2c [LI]	Records	0 (0%)	1 (100%)	0 (0%)	2 (20%)	8 (80%)	0 (0%)	
		2.11.C #4 [HR]	Records	0 (0%)	1 (100%)	0 (0%)	0 (0%)	10 (100%)	0 (0%)	
		2.11.D #5 [LU]	Records	0 (0%)	1 (100%)	0 (0%)	0 (0%)	10 (100%)	0 (0%)	
		2.11.E #5 & #6 [PA]	Records	0	0	0	0 (0%)	7 (100%)	0 (0%)	
		2.13 #5	Records	0 (0%)	1 (100%)	0 (0%)	1 (10%)	9 (90%)	0 (0%)	
		2.14.B	Records	0 (0%)	0 (0%)	1 (100%)	2 (20%)	8 (80%)	0 (0%)	
		2.14.C #6	Records	0 (0%)	1 (100%)	0 (0%)	2 (20%)	6 (60%)	2 (20%)	
		2.2 #14	Records	0 (0%)	1 (100%)	0 (0%)	4 (40%)	2 (20%)	4 (40%)	
		2.2 #15	Records	0 (0%)	1 (100%)	0 (0%)	1 (10%)	9 (90%)	0 (0%)	
		2.2 #2	Records	0 (0%)	1 (100%)	0 (0%)	0 (0%)	10 (100%)	0 (0%)	
		2.2 #5	Records	0 (0%)	1 (100%)	0 (0%)	0 (0%)	10 (100%)	0 (0%)	
		2.3	Records	0 (0%)	1 (100%)	0 (0%)	0 (0%)	10 (100%)	0 (0%)	
		2.4	Records	0 (0%)	1 (100%)	0 (0%)	0 (0%)	10 (100%)	0 (0%)	
		2.5	Records	0 (0%)	1 (100%)	0 (0%)	0 (0%)	9 (90%)	1 (10%)	
		2.6.B	Records	0 (0%)	1 (100%)	0 (0%)	2 (20%)	8 (80%)	0 (0%)	
		2.8 #7	Records	0 (0%)	1 (100%)	0 (0%)	3 (30%)	6 (60%)	1 (10%)	
		2.9 #1	Records	0 (0%)	1 (100%)	0 (0%)	1 (10%)	9 (90%)	0 (0%)	
		2.9 #2	Records	0 (0%)	1 (100%)	0 (0%)	0 (0%)	10 (100%)	0 (0%)	
		2.9 #3*	Records	0 (0%)	1 (100%)	0 (0%)	0 (0%)	10 (100%)	0 (0%)	
		Accuracy of	Records	0 (0%)	1 (100%)	0 (0%)	0 (0%)	10 (100%)	0 (0%)	
		Serologies								
Living Donor	LDK	13.4.A (LDK)	Records	0 (0%)	1 (50%)	1 (50%)	1 (20%)	4 (80%)	0 (0%)	
		13.4.C (LDK)	Elements	1 (50%)	0 (0%)	1 (50%)	2 (50%)	1 (25%)	1 (25%)	
		14.4.B	Elements	24 (34.29%)	38 (54.29%)	8 (11.43%)	20 (21.05%)	70 (73.68%)	5 (5.26%)	
		18.5.A (Accuracy) KI 6 months	Elements	3 (15%)	10 (50%)	7 (35%)	7 (20%)	16 (45.71%)	12 (34.29%)	
		18.5.A (Accuracy) KI one year	Elements	1 (25%)	2 (50%)	1 (25%)	2 (22.22%)	6 (66.67%)	1 (11.11%)	
	LDL	14.4.C	Elements	3 (23.08%)	10 (76.92%)	0 (0%)	7 (36.84%)	12 (63.16%)	0 (0%)	
		18.5.B (Accuracy) LI 6 months	Elements	1 (25%)	3 (75%)	0 (0%)	2 (66.67%)	1 (33.33%)	0 (0%)	
	Non-	14.1.A	Elements	26 (31.33%)	14 (16.87%)	43 (51.81%)	49 (42.98%)	34 (29.82%)	31 (27.19%)	25
	specified	14.2.A	Elements	9 (10.98%)	28 (34.15%)	45 (54.88%)	36 (31.58%)	67 (58.77%)	11 (9.65%)	45

14.3	Elements	40 (48.78%)	6 (7.32%)	36 (43.9%)	71 (62.28%)	17 (14.91%)	26 (22.81%)	21
14.4.A	Elements	48 (57.83%)	17 (20.48%)	18 (21.69%)	74 (64.91%)	27 (23.68%)	13 (11.4%)	10
14.5.A/14.5.B	Elements	6 (7.23%)	75 (90.36%)	2 (2.41%)	6 (5.26%)	106 (92.98%)	2 (1.75%)	
14.5.C	Elements	0 (0%)	82 (98.8%)	1 (1.2%)	1 (0.88%)	113 (99.12%)	0 (0%)	
14.7	Records	32 (45.71%)	22 (31.43%)	16 (22.86%)	44 (45.36%)	50 (51.55%)	3 (3.09%)	20
18.1 (Accuracy)	Elements	27 (32.53%)	11 (13.25%)	45 (54.22%)	47 (41.23%)	28 (24.56%)	39 (34.21%)	20
18.1 (Timely)	Records	24 (28.92%)	41 (49.4%)	18 (21.69%)	26 (22.81%)	69 (60.53%)	19 (16.67%)	

* Aggregate audit data is available several months after audits are performed, and data from some audits between March 31, 2022 – June 30, 2022 are not yet available. In order to not misrepresent that quarter, it is not included in this table.

Table 7 shows the quantity of pairs of all routine transplant recipient site surveys where the program had two routine site surveys between January 1, 2016 and June 30, 2022 where a specific policy was reviewed. It compares the compliance rate of the first (2nd most recent) and second (most recent) surveys within those survey pairs for those policies, and indicates whether those rates decreased, increased or stayed the same. It also divides survey pairs into two cohorts based on whether a pair's first survey resulted in a recommendation for a desk review. The eighth column of the table indicates the percentage point difference between cohorts in the proportion of survey pairs where compliance rate increased. Included and highlighted are policies where there were 10 or more total elements or records reviewed in each cohort, and there was a 10 point or larger difference between cohorts in the percentage of total surveys where there was an increase in policy compliance rates. For all of such policies, the cohort with a desk review between surveys had a greater percentage of increases in policy compliance rates than the non-desk review cohort.