

OPTN Membership and Professional Standards Committee

Meeting Summary

July 22-24, 2025

Conference Call

Cliff Miles, M.D., Chair

Scott Lindberg, M.D., Vice Chair

Introduction

Membership and Professional Standards Committee (MPSC) met virtually via Webex in closed and open session on July 22-24, 2025, to discuss the following agenda items:

1. HRSA Remarks
2. MPSC Project Overview
3. Report of Investigative Activities
4. MPSC Education/Communication Initiatives and Policy Referrals
5. Performance Monitoring Enhancement Update
6. MPSC Operational Projects
7. Membership Issues
8. Performance Issues
9. Compliance Issues

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

1. HRSA Remarks

The Organ Transplantation Branch Chief, Division of Transplantation, HHS addressed the Committee. He informed attendees that a hearing had just concluded with the House Oversight and Investigations Subcommittee, part of the Committee on Energy and Commerce. The hearing focused on patient safety within the system, a topic that has recently gained attention in mass media. He emphasized the critical role that MPSC plays in ensuring the safety of all patients who interact with the system and expressed his gratitude to the volunteers for their willingness to serve.

He reassured attendees that HRSA is committed to supporting its volunteers by offering input and direction as they move forward. He reiterated his organization's open-door policy and encouraged anyone with questions to reach out directly to him via email. He concluded his remarks by thanking everyone for their dedication and service.

2. MPSC Project Overview

Contractor staff provided an overview of the status and expected future work for one MPSC project, Incorporate Multi-Organ Post-Transplant Graft Survival into Performance Evaluations, that is in the project approval phase of the policy development process and three projects, Enhance Transplant Program Performance Monitoring, Update Criteria for Post-Transplant Graft Survival, and Require Reporting of Patient Safety Events, that are in the post-implementation phase. Staff reviewed the current roster for the Performance Monitoring Enhancement Subcommittee that is engaged in post-implementation monitoring and evaluation of performance case review processes and requested volunteers for the subcommittee. Staff also noted that volunteers for a potential future workgroup for

the Incorporate Multi-Organ Post-Transplant Graft Survival into Performance Evaluations project were needed.

Summary of discussion:

No decisions were made but committee members expressed their interest in volunteering for the MPSC subcommittees or workgroups through a poll.

The Committee had no questions or comments.

3. Report of Investigative Activities

The Patient Safety Team outlined the reporting process and types of cases reviewed on the compliance agenda, emphasizing the importance of understanding the structure and purpose of reports included in meeting packets. These reports, either investigative or aggregate summaries, are meant for independent review, with opportunities to raise questions during meetings. Investigative reports compile concerns from various sources, including OPTN members, HRSA, patients, families, and anonymous individuals. Most are voluntary, except those required under Policy 18.5 *Reporting of Patient Safety Events*. Each report is assessed for patient safety risks, system integrity issues, or policy violations.

Reports are submitted through multiple channels, such as the OPTN Computer System portal, member reporting line, patient services, disease transmission referrals, automated alerts, email, mail, and media. All reports are triaged within two hours, including weekends, and investigated using systems like the OPTN Donor Data and Matching System and OPTN Computer System. If a report lacks sufficient detail or falls outside OPTN's scope, it may be marked "reviewed and cleared" but remains accessible for future reference.

The investigative process involves inquiries to members, data collection, and review by an interdisciplinary committee, which decides whether to refer cases to the MPSC based on systemic risk or policy violations. Duplicate reports are consolidated, and only significant cases are referred. Monthly and quarterly reports provide metrics, case statuses, and trend analyses to support policy development and education.

Emerging issues, such as increased Normothermic Regional Perfusion (NRP) cases, have prompted subcommittees and broader discussions, even though NRP is not yet addressed in policy. Reports may span multiple periods due to complexity, and the team strives for consistent triage and equitable treatment. Transparency is prioritized, and committee feedback helps refine processes.

Summary of Discussion

No decisions were made but OPTN Contractor Staff committed to improving clarity while maintaining context in the reports.

During the discussion, a committee member asked about the inclusion of past investigation details in reports, noting that it can sometimes obscure the focus of current cases. Staff acknowledged the feedback and committed to improving how historical context is presented while maintaining a holistic view of member behavior.

Staff explained that as a contractor, the team maintains ongoing communication with HRSA to ensure alignment with expectations and investigative standards. While the staff adheres to a structured

process, it also embraces performance improvement and is open to refining methods based on trends and feedback.

The staff is open to performance improvements. The chair highlighted the value of post-meeting summaries and encouraged feedback on report structure and presentation, reinforcing the importance of these reports in understanding member quality issues.

4. MPSC Education/Communication Initiatives and Policy Referrals

OPTN Contractor Staff facilitated a discussion of the Committee on OPTN updates, previous policy referrals, potential new policy referrals, and topics for the MPSC chair email. Staff discussed each ongoing effort and the MPSC had questions and offered feedback.

OPTN Updates

OPTN Contractor Staff provided an overview of recent OPTN updates including ongoing HRSA Directive work on normothermic regional perfusion (NRP), donation after circulatory death (DCD) policy, rabies transmission, and allocation out of sequence (AOOS). The MPSC was also updated on the start of the new Board of Directors' term on July 1, 2025, as well as the prior resolution in June that discontinued non-critical meeting support for committees without active projects, with an exemption for the Patient Affairs Committee (PAC). Finally, the Committee received an update on the HRSA directed pause on continuous distribution (CD) work by the organ specific committees.

Policy Referrals

OPTN Contractor Staff provided an overview of the referral process, highlighting the information the MPSC needed to align on before sending a policy referral, and topics of past referrals. To date, the MPSC has sent 18 referrals to eleven policy committees since the development of this process in early 2023. Of the 18, three referrals have results in projects that have been implemented, 2 are OPTN Board approved and pending implementation, 9 are in development or pending approvals, and 4 are on hold or not approved by either the OPTN Executive Committee or the referred committee. Staff provided updates on the following referrals:

- Clarify Discrepant ABO Typing Post-Transfusion
 - Jointly referred to the Operations and Safety (OSC) and Histocompatibility Committees in December 2024. Histocompatibility Committee leading project and seeking POC approval in September.
- Pediatric Heart Data
 - Jointly referred to the Pediatric and Heart Transplantation Committees in December 2024. Pediatric Committee is interested in taking on project but slating behind their current project on Loss to Follow Up Data.
- Develop Competencies for Qualified Health Professional
 - Jointly referred to the OSC and Histocompatibility Committees in March 2025. Both committees declined to take on the project at this time due to competing priorities.
- Heart Review Board Comparative Analysis
 - Referred to Heart Transplantation Committee in March 2025. Heart Committee leadership met with MPSC leadership and subject matter experts (SMEs) to discuss. The Heart Committee was originally planning to integrate review board changes into their CD framework, but with the recent pause in CD work there are reconsiderations of next steps for Heart Committee work.

Staff also provided updates on the following proposals based on referrals that have been approved by the OPTN Board of Directors and are pending implementation before the end of 2025:

- *Standardize the Patient Safety Contact and Reduce Duplicate Reporting- Ad Hoc Disease Transmission Advisory Committee (DTAC)*
- *Clarify Requirements for Reporting Post-Transplant Diseases – DTAC*
- *Monitor Ongoing eGFR Modification Policy Requirements – Minority Affairs Committee (MAC)*

Additionally, there have been two memos sent to other OPTN Committees by the MPSC that the Committee was updated on:

- MPSC Feedback for the OPO Committee on the Machine Perfusion and NRP Data Collection Project
 - Sent April 2025 and suggested additional data fields including allowing data collection for multiple devices per organ, collecting the device user, and adding a data field for hematocrit. The feedback was incorporated into proposal drafted for public comment.
- MPSC Memo to the Patient Affairs and Living Donor Committees (LDC) Regarding Living Donor Deaths
 - Sent July 2025 and noted an anecdotal increase in living donor patient safety events that the MPSC believes warrants a system wide evaluation of OPTN data. Currently under review by PAC and LDC leadership.

MPSC members did not have any questions about the existing referrals or the referral process, so the floor was opened to discuss any potential new referrals.

Summary of discussion:

Decision: The MPSC will not send any referrals following this meeting.

The MPSC Chair began the conversation by noting that many of the topics the Committee considers such as AOOS and improving allocation are already in the works as part of directives or other ongoing project work, and so it might be beneficial to consider giving those groups some time to work. A Committee member asked about referral the addition of data fields for donor support therapies, and staff clarified that the OSC has a project to add that data collection that has been Board approved and is just waiting for Office of Management and Budget (OMB) approval to implement. Several other members noted the importance of improving organ allocation and DCD policies given the recent focus on those topics. The Committee decided to consider those topics for the Chair Email but not to send out any referrals following this meeting.

MPSC Chair Email

The Committee reviewed past MPSC Chair email topics and discussed the key takeaways from the multiday meeting to share back to the community. OPTN Contractor highlighted some previous, relevant messages that the MPSC has shared in order to further refine and add more granularity to this chair email.

Summary of Discussion:

MPSC members highlighted growing concerns about cases where first-person authorization for organ donation exists, yet families are unwilling to proceed. This area, particularly in DCD contexts, was described by members as “murky” and lacking national consistency. There was broad agreement that clearer standards and national guidelines are needed, and suggestions were made to involve professional societies in shaping these guidelines.

The conversation also explored tension between OPOs and transplant hospitals, with participants noting that current policy structures can place them at odds—OPOs focus on maximizing organ recovery, while

transplant hospitals prioritize outcomes and risk minimization. This misalignment was cited as a barrier to collaboration and patient-centered decision-making.

Another key theme was the urgent need for improved and standardized education for staff involved in organ allocation and transplant processes. High staff turnover and inconsistent training were noted as contributing to a lack of policy awareness. The MPSC proposed including references to existing educational resources—such as those from the OPTN Learning Management System, NATCO, and The Alliance—in the Chair’s upcoming community email. There was also support for developing standardized competencies or expectations for professional education across institutions.

The Committee discussed which topics should be addressed in the upcoming Chair email. It was agreed that the message should focus primarily on the need for education and training, using DCD confusion and recent match rerun errors as illustrative examples rather than headline issues. A separate concern raised by a committee member involved occasional potential defects in HLA typing kits, but the MPSC decided that it did not need to be included in the Chair email.

5. Performance Monitoring Enhancement Update

Presentation topics included the biannual transplant program performance monitoring summary data based on the July 2025 Scientific Registry of Transplant Recipients (SRTR) reports and proposed updates to the post-transplant outcomes questionnaire and staff summary.

OPTN Contractor Staff reviewed data for transplant programs flagged in July 2025 for all four performance monitoring metrics based on the SRTR MPSC reports. The data presented included the following:

- Number and percentage of active programs flagged overall and by organ
- Number of flags for each organ type for each metric including total number of flags for each metric
- A comparison of adult vs pediatric flags
- Number of programs flagged for review by metric and cycle
- Number of programs flagged by organ and cycle
- Number of programs flagged over multiple report cycles and newly identified this cycle.

Staff noted that programs that are flagged, undergo review, and then released are given a one-year grace period before they are required to re-enter MPSC performance review if they continue to be flagged. This operational rule accounts for the fact that MPSC reviewers have likely reviewed the events resulting in the flagging during that year after release because of the time lag in the SRTR metrics.

The Committee reviewed the Performance Monitoring Enhancement Subcommittee’s recommendations for revisions to the post-transplant outcomes questionnaire that is sent to programs flagged for 90-day post-transplant and 1-year conditional on 90-day post-transplant graft survival and the staff summary that is included in the MPSC post-transplant graft survival case packets.

Summary of discussion:

Decision: The Committee approved the revisions to the post-transplant outcomes questionnaire and staff summary by a vote of 24 yes, 0 no, 0 abstained.

A committee member asked whether there has been an increase in the number of transplants following the implementation of the flagging criteria change for the two post-transplant graft survival metrics. The

data presented shows the decrease in the number of programs flagged based on the revised criteria. Staff noted that the data on the number of transplants and other more detailed data will be in the annual post-implementation monitoring report that is scheduled to be presented at the November 2025 MPSC meeting.

The Committee approved the revisions to the post-transplant outcomes questionnaire and staff summary by a vote of 24 Yes, 0 No, 0 Abstained.

The Committee had no questions or comments.

Brief summaries are provided below for the issues (6-9) discussed in closed session:

6. MPSC Operational Projects

OPTN Contractor staff provided an overview of the status and expected future work for two MPSC operational projects, Third Party Vendor Review and Allocation Review. MPSC operational projects focus on the review, development, and/or revision of MPSC review processes, not changes to policy although they may recommend referrals to other committees for policy revisions if that need is identified. Operational Subcommittees may also be used to review certain case types.

Staff reviewed the rosters for the Third-Party Vendor Review Subcommittee and the Allocation Review Subcommittee and requested volunteers for these subcommittees.

Decision: No decisions were made.

7. Membership Issues

Decision: The Committee approved the membership consent agenda by a vote of 24 Yes, 0 N, and 0 Abstained.

The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants and applications are presented to the MPSC members as either a consent or discussion agenda. The Committee reviewed and approved the consent agenda by a vote of 24 Yes, 0 No, and 0 Abstained.

The Committee considered the applications and other actions listed below and will ask the Board of Directors to approve the following recommendations during the December 2025 meeting as listed below.

- Conditionally approve 1 Component
- Approve 11 Business membership renewals

The Committee also reviewed and approved the following program related actions and personnel changes.

- 39 applications for changes in key personnel in Transplant Programs or Components
- 3 applications for changes in key personnel in Histocompatibility Laboratories
- 2 applications for changes in single physician programs

The Committee received notice of the following Inactivation and withdrawal changes.

- 1 notice of a program inactivation
- 2 notices of program withdrawals

8. Performance Issues

Performance Consent Agenda

Decision: The Committee approved the performance consent agenda by a vote of 21 Yes, 0 No, and 0 Abstained.

For transplant programs under review for lower than expected 90-day graft survival rates and 1-year graft survival conditional on 90-day survival rates, the Committee approved the continued monitoring of 10 transplant programs: two heart programs for 1-year conditional; two kidney programs for 90-day, one kidney program for 1-year conditional; four liver programs for 90-day, and one liver program for 1-year conditional. Additionally, the Committee approved the release of monitoring of four transplant programs: one kidney program for 90-day, one kidney program for 1-year conditional; one liver program for 90-day; and one pancreas program for 1-year conditional.

For transplant programs under review for offer acceptance, the Committee approved the continued monitoring of 19 transplant programs: 12 kidney programs, three liver programs, and four lung programs. Additionally, the Committee approved the release of monitoring of one kidney program.

For transplant programs under review for pre-transplant mortality, the Committee approved the continued monitoring of 10 transplant programs: five heart programs, one kidney program, two liver programs, and two lung programs. Additionally, the Committee approved the release of monitoring of one heart transplant program.

For transplant programs under review for functional inactivity, the Committee approved the continued monitoring of four transplant programs: one heart program and three pancreas programs. Additionally, the Committee approved the release of monitoring of four transplant programs: one heart program, one kidney program, and two pancreas programs.

For organ procurement organizations (OPO) under review for donor yield, the Committee approved the continued monitoring of three OPOs.

The Committee approved the performance consent agenda by a vote of 21 Yes, 0 No, and 0 Abstained.

The Committee also discussed cases in closed session.

9. Compliance Issues

Decision #1: The Committee approved the compliance consent agenda by a vote of 22 Yes, 1 No, and 0 Abstained

The Committee reviewed a consent agenda consisting of 6 transplant programs that had undergone a focused desk review during this cycle, including 1 heart program, 4 kidney programs, and 1 lung program. The Committee released 5 of those programs from monitoring and recommended a focused desk review for 1 program. The Committee also reviewed 2 transplant hospitals for allocation errors and issued 2 notices of noncompliance. The Committee determined that it would remove the other 12 OPO reviews from the consent agenda and review them at an upcoming meeting, as the discussion around allocations out of sequence evolves. The Committee reviewed 56 case investigations during this cycle, consisting of member complaints or self-reported potential policy violations. The Committee issued 27 Notices of Noncompliance and closed 29 issues with no action, 27 of which were closed for self-reporting. In addition, the Committee reviewed 18 reported living donor events this cycle. 7 events were aborted nephrectomies, all of which were reported within required timeframes and closed with no action. 3 aborted hepatectomies were also closed with no action for appropriate reporting. There were 8 living donor redirections; 5 all reported on time and closed with no action and 3 issued a Notice of Noncompliance for late reporting.

The Committee approved the consent agenda by a vote of 22 Yes, 1 No, and 0 Abstained.

The Committee also discussed cases in closed session.

Upcoming Meeting

- August 22, 2025, 2:30-5pm, ET
- September 26, 2025, 2:30-5:30pm, ET
- November 5-7, 2025, Details TBD
- December 5, 2025, 3-4pm, ET
- December 12, 2025, 2-5pm, ET

Attendance

- **Committee Members**
 - Bradley Adams
 - Abbas Ardehali
 - Mitzi Barker
 - Megan Bell
 - David Bruno
 - Michael Daily
 - Chad Denlinger
 - Amishi Desai
 - Niraj Desai
 - Chad Ezzell
 - Roshan George
 - Darla Granger
 - Dipankar Gupta
 - Shelley Hall
 - Richard Hasz
 - Nicole Hayde
 - Kyle Herber
 - Lindsay King
 - Varvara Kirchner
 - Kevin Koomalsingh
 - Kevin Korenblat
 - Pete Lalli
 - Scott Lindberg
 - Maricar Malinis
 - Michael Marvin
 - Deborah Maurer
 - Clifford Miles
 - Saeed Mohammad
 - Kenneth Newell
 - Anthony Panos
 - Deirdre Sawinski
 - Paul Stahler
 - Carrie Thiessen
 - James Yun
- **HRSA Representatives**
 - James Bowman
 - Shantel Delgado
 - Marilyn Levi
 - Joni Mills
 - Arjun Naik
 - Kala Rochelle
- **SRTR Staff**
 - Jonathan Miller
 - Jon Snyder
 - Bryn Thompson

- David Zaun
- **UNOS Staff**
 - Robert Albertson
 - Sally Aungier
 - Jadia Bruckner
 - Nadine Cahalan
 - Aileen Corrigan-Nunez
 - Tommi Dawson
 - Katie Favaro
 - Liz Friddell
 - Shavon Goodwyn
 - Asia Harden
 - Houlder Hudgins
 - Heather Neil
 - Delaney Nilles
 - Emily Powell
 - Tina Rhoades
 - Liz Robbins
 - Melissa Santos
 - Laura Schmitt
 - Erin Schnellinger
 - Sharon Shepherd
 - Sarah Stevenson
 - Stephon Thelwell
 - Melissa Tisdale
 - Betsy Warnick
 - Trevi Wilson
 - Hollie Woodcock
 - Karen Wooten
 - Amanda Young
 - Amanda Zamora
- **Other Attendees**
 - None