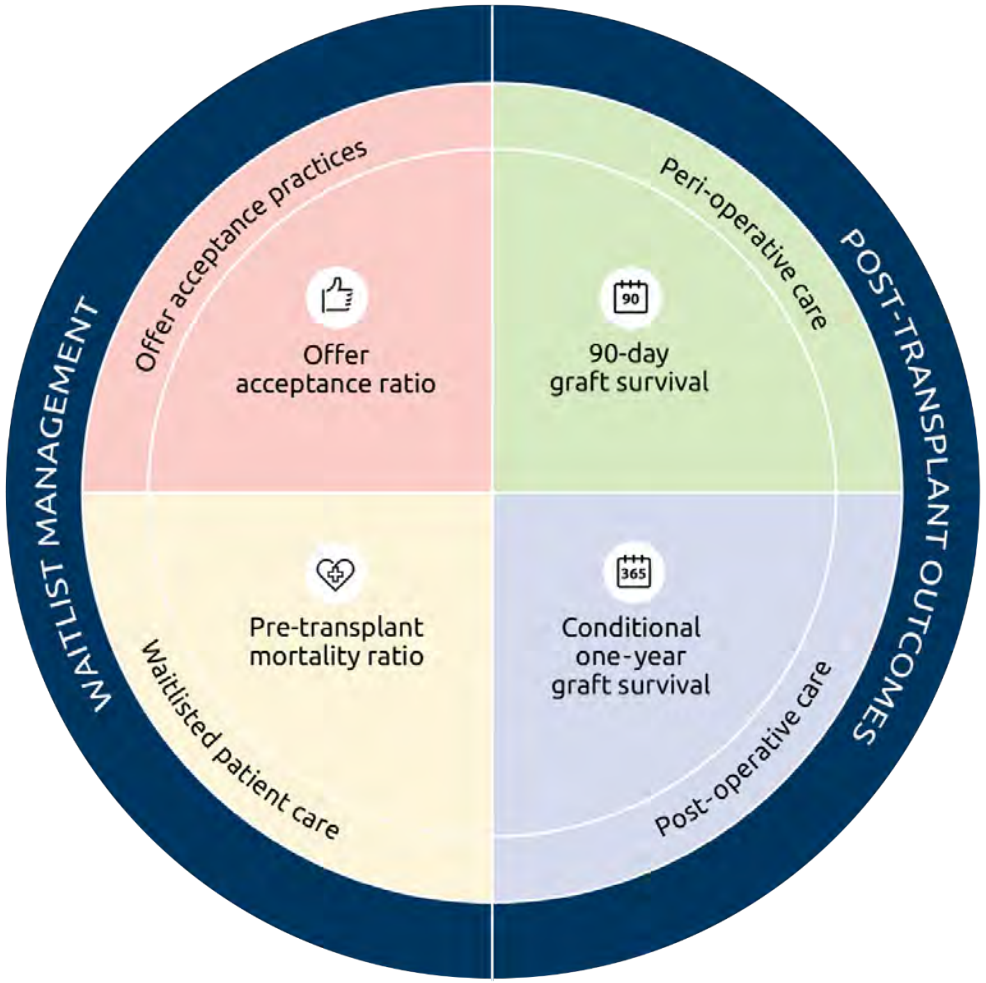
OPTN Membership and Professional Standards Committee (MPSC) and Member Quality Update

Winter 2025

MPSC Topics and Initiatives

- Committee Projects
- Increasing Public Disclosure
- Monitoring Activities
- Compliance Data

Transplant Program Performance Monitoring



Implementation Timeline

Implemented July 2022:

- 90-day graft survival hazard ratio
- One-year graft survival conditional on 90-day graft survival hazard ratio

Implemented July 2023:

- Offer acceptance rate ratio
- First offer cohort: 1/2022 – 12/2022

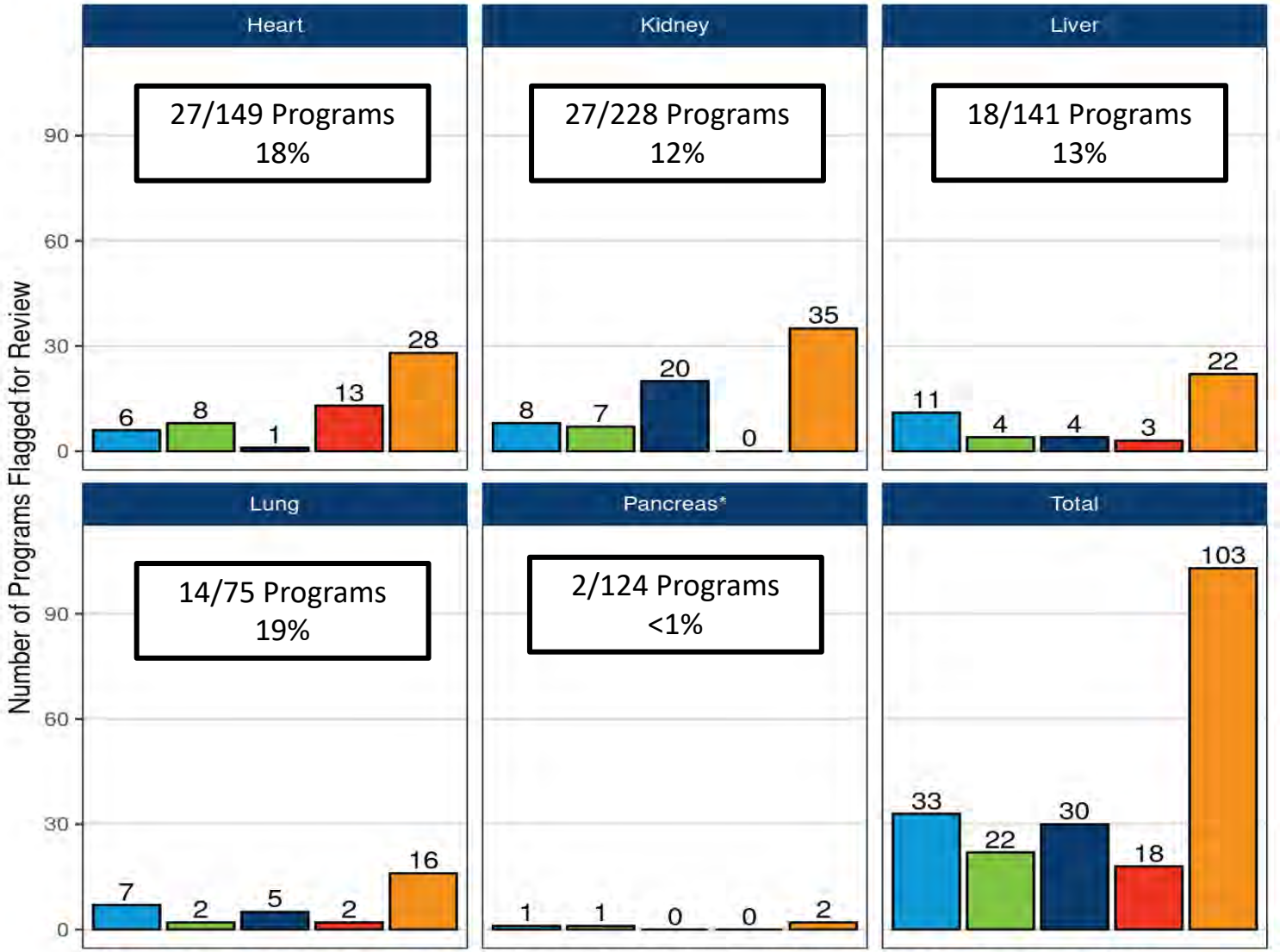
Implemented July 2024:

- Pre-transplant mortality rate ratio
- First Observation window: 1/2022 – 12/2023

July 2024 Flags

MPSC determines a flagging threshold for each performance metric, designed to identify outlier programs.

- 717 total Programs as of 7/15/2024
- 103 flags for 91 individual active programs (12.7%)
  - 5 kidney and 3 liver programs were previously withdrawn
  - 7 programs were flagged for more than 1 metric – 1 heart, 3 kidney, 1 liver, 2 lung



** Pancreas programs are reviewed based on patient survival rather than graft survival. Pancreas programs are not reviewed based on 90-day patient survival, only 1-year conditional patient survival for post-transplant metrics.*

Number of programs (Adult and Pediatric) flagged for review by metric and organ, Spring 2024

90-Day Graft Survival
1-Year Conditional Graft Survival
Offer Acceptance Rate
Pre-Transplant Mortality Rate
Total

Transplant Program Performance Monitoring

- Second annual post-implementation monitoring report reviewed in November
- Overall Summary
  - Observed trends in one-year all-cause graft failure rates were **similar or lower (better)** than predicted trends post-Board approval for all organs
  - Observed trends in waiting list additions were **similar or higher (better)** than predicted trends post-Board approval for all organs
  - Observed trends in utilization rates and transplant-to-recovery rates tended to be **similar or higher (better)** than predicted trends post-Board approval for all organs

Updated Post-Transplant Graft Survival Criteria

- Purpose
  - Encourage utilization of more clinically complex donor organs
  - Remove barriers to increasing the number of transplants
  - Reduce transplant program concern about potential MPSC performance review
  - Support Expeditious Task Force bold aim of 60,000 deceased donor transplants by 2026
- Changes the thresholds for adult 90-day graft survival and 1-year conditional on 90-day graft survival metrics
  - Current threshold: 50% probability that graft survival hazard ratio is greater than 1.75
  - New threshold: 50% probability that graft survival hazard ratio is greater than 2.25
- Implementation date: March 6, 2025

OPO Performance Monitoring

- Project on hold at the request of HRSA as of January 16, 2024
- OPTN Executive Committee postponed release of concept paper to avoid confusion between concept paper and expected HHS Secretarial Directive that would include data collection on ventilated referrals
- Workgroup collaboration with the Data Advisory Committee (DAC) on draft OPTN comment to 60-day Federal Register Notice on HRSA directive data collection
- Data request for SRTR presentation on SRTR risk-adjusted OPO performance metrics

Membership Requirements Revision

- Proposal was scheduled to be released during Winter 2025 public comment addressing:
  - Appendix B: OPO Membership Requirements
  - Appendix D: Transplant Hospital Membership and Designated Transplant Program Requirements
- Future work planned to address organ-specific key personnel training and experience requirements in Appendices E – J
- Project on hold at the request of HRSA as of January 22, 2025, based on concerns about whether was within scope of the OPTN Final Rule and intent to evaluate membership requirements as part of the OPTN Modernization effort

Increasing Public Disclosure

- Annual update of OPTN Compliance and Evaluation page
  - Included a full review and update to the OPTN Member Evaluation Plan (EP) to better reflect how the OPTN monitors members for compliance with OPTN Policies
    - Updates made to the monitoring language for over 50 policies in the EP
- MPSC Resources page
  - Avoiding ABO determination failures
  - Avoiding pre-transplant verification failures
- Soliciting feedback from MPSC members and community
  - Patient safety event intake process
  - Sharing living donor required reports and outcomes
  - Sharing MPSC member experiences to broader community

MPSC Chair Emails

- Purpose: To disseminate learnings and effective practices observed during MPSC meetings and interactions with OPTN members
- Shared with the community after each in-person MPSC meeting
- Previous themes include:
  - Best practices for reporting Patient Safety events, organ verification, and ABO verification
  - DCD organ recovery pre-OR huddles
  - Network security requirements
  - Reporting of third-party vendor issues and medical device malfunction
  - Allocation out of sequence and hard-to-place organs
  - Recommendations regarding living donor and paired exchange related events

Allocation Reviews

- In April 2024, the MPSC utilized their new allocation monitoring operational rules
- Most cases are closed with no action due to the OPO acting to get the organs placed and reduce the risk of non-use

MPSC Meeting	Allocation Deviations Reviewed
July 2022	500
October 2022	820
February 2023	758
July 2023	795
November 2023	1529
April 2024	695
July 2024	675

*Allocation Deviations includes the total number of organ allocations reviewed by the MPSC

Site Survey

- Routine surveys
  - Policy compliance generally improves after initial monitoring cycle
  - New policies face higher non-compliance risks, often requiring follow-up reviews

- Continuous Monitoring
  - Automated reports based specific triggers in OPTN Computer System
  - Request corrective action or remediation with faster turnaround than routine surveys

- Surveys conducted June 2024 – November 2024
  - Transplant Hospitals: 36 routine site surveys, 37 desk reviews
  - OPOs: 9 routine site surveys, 1 desk review

Investigations

- Reports are received through the Safety Situations and Living Donor Event sections of the OPTN Patient Safety and Reporting Portal, the Member Reporting line, and other pathways
  - Reports are investigated by analyzing the information in the report and sending inquires to the member(s)
  - 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
- Every report is triaged to assess the potential risk to patient safety/public health and determine if an investigation is needed
- HRSA Reportable Events are specific patient safety events that pose a serious or time-sensitive threat to public health or patient safety

Patient Safety Reporting

Patient safety reports received from June 1, 2024 – October 27, 2024

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

Patient Safety – Case Classifications

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

- Patient Safety did not identify any remarkable deviations in the trending of event classifications compared to the data reported last cycle
- Patient Safety continues to see a number of reported events falling into 3 categories: Organ and Extra Vessels, Deceased Donor Organ Procurement, and Other
  - Organ packaging/labeling/shipping, reports of surgical damage, member-specific allegations, donor management and donor recovery issues remain the most commonly reported event types

Compliance Reviews

- There have been increases in informal discussions and peer visits to intervene early and help programs before issues become severe
- All compliance reviews June 2024 – November 2024:

MPSC Action	Allocation Reviews	Site Surveys	Investigations
Close with no action	46	31	58
Follow up survey	n/a	14	n/a
Notice of Noncompliance	0	1	66
Letter of Warning	0	0	0
Probation	0	0	0
Member Not in Good Standing	0	0	0
Informal Discussions	0	1	9
Interviews	0	0	1
Peer visits	0	1	2

Feedback or Questions

- If you have feedback or questions on topics covered today, email MQFeedback@unos.org