OPTN Policy Oversight Committee
Meeting Summary
June 12, 2025
Teleconference
Jennifer Prinz, BSN, MPH, Chair
Erika Lease, MD, Vice Chair

Introduction

The OPTN Policy Oversight Committee ("POC" or "the Committee") met via teleconference on 06/12/2025 to discuss the following agenda items:

1. Welcome and updates
2. New Project Review: *Incorporate Multi-Organ Post-Transplant Graft Survival into Performance Evaluations*
3. Post-Implementation Review: Modify Data Submission Policies
4. Summer 2025 Public Comment Preview

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

1. Welcome and updates

The Committee was informed the OPTN Executive Committee and Board of Directors approved the two new projects presented previously, *Modify Lung Allocation by Candidate Biology* and *Inactive Status Notifications*. These projects will begin development by their relevant committees. OPTN Contractor staff (staff) informed the Committee that the July POC meeting will be extended to 90 minutes to accommodate review of all projects going out for public comment.

2. New Project Review: *Incorporate Multi-Organ Post-Transplant Graft Survival into Performance Evaluations*

The Vice Chair of the Membership and Professional Standards Committee (MPSC) presented the new project. It was noted that while this project does not require policy revision, the MPSC felt it appropriate to put out for public comment prior to making these performance evaluation changes.

Summary of discussion:

The Committee voted to recommend the project to the Executive Committee for approval. 14 yes, 0 no, 0 abstain.

A member raised a question about whether the project will track which specific organ fails in multi-organ transplants, as this is essential for measuring outcomes accurately. They asked if the data will be broken down by organ type, noting that while kidney failure is common, it's important to know which organ fails in a multi-organ graft, as well as how and why it happens.

The MPSC Vice Chair agreed that this is a central issue for the project—specifically, how to define graft failure in multi-organ transplants and determine who is accountable for the failure. They pointed out that kidney outcomes are often closely scrutinized, especially because kidneys used in multi-organ

transplants tend to be of very high quality and are expected to have strong survival rates. They also acknowledged a broader question: How do outcomes in multi-organ transplants compare to outcomes in kidney-only transplants, once risk factors are adjusted? Should these multi-organ transplant cases, like liver-kidney transplants, be evaluated as their own category, or should they be compared to the general kidney-alone population?

Staff requested Committee input on assigning a benefit score of 91 to the project. The Committee Vice Chair expressed uncertainty about the project's measurability, noting that since it does not involve a policy change, it's unclear how a decrease in outcomes could be expected as monitoring alone may not directly lead to measurable changes. From a thoracic perspective, the Vice Chair noted that multi-organ transplant patients typically arrive in much more critical condition, which affects their survival rates post-transplant. They invited input from other members on how this project might intersect with the proposed changes to multi-organ allocation currently in development.

The MPSC Vice Chair acknowledged the concern that implementing two initiatives simultaneously could make it difficult to determine which one is driving any observed changes. They emphasized that monitoring and measuring quality is central to MPSC's mission. One goal of this project is to see whether it influences program behavior, for example, whether transplant centers become more risk-averse when performing multi-organ transplants. They agreed, however, that measuring this behavioral change would be challenging and supported the idea of removing measurability from the benefit score. Despite that, they advocated for continuing the project, affirming that it is important work and closely aligned with the MPSC's core goals.

The Committee Vice Chair agreed, suggesting that even with a lower score which excludes measurability, the project would still fall within an acceptable range for approval. The MPSC Vice Chair concurred, adding that the project would still qualify as low-cost and high-benefit. They also noted that the current cost estimate reflects a worst-case scenario, and actual costs are expected to be lower. It was clarified that approximately 1,399 patients would be affected, mainly those receiving heart-kidney or liver-kidney transplants, as outcomes for kidney-pancreas transplants are already being monitored. Reflecting discussion, the project's benefit score was adjusted to 74.

The discussion leader shared their comments on the project, stating that it is well-timed and that no other initiatives should take priority over it. They emphasized that the project offers strong benefits at a relatively low cost, an important consideration given the OPTN's current focus on cost-efficiency. While they did not believe this project needs to be prioritized over others in development, they noted that it does not conflict with the goals of any other ongoing Committee work not already discussed.

One potential risk they identified is that the project could lead transplant centers to become more risk-averse in performing multi-organ transplants. They pointed out this trend is already being observed in liver transplantation and expressed concern that further pressure could discourage the use of multi-organ transplants. However, they also agreed that monitoring these outcomes is critical to ensuring the equitable and effective use of donor organs.

They stressed the need for the proposal to clearly outline its methodology, whether the analysis will be organ-specific and whether the failed organ will be identified. These elements are essential for accurately understanding how multi-organ transplants are being used and assessed.

The discussion leader raised the possibility of other unintended consequences. For example, if transplant centers perceive that negative outcomes from high-risk transplants will be tracked and potentially penalized, they may stop offering these procedures. This could alter transplant access, particularly in cases where eligibility decisions are influenced not only by medical need but also by socioeconomic or behavioral factors—potentially increasing disparities. Finally, they noted concerns

about the small sample size involved. For instance, if a liver program performs five simultaneous liver-kidney (SLK) transplants and one patient dies, that results in an 80 percent survival rate, but the significance of such a statistic is limited by the small denominator. They also observed that transplants like heart-liver and liver-lung are excluded from the project due to low volume, and even with approximately 1,000 SLK cases across 140 liver programs, the data may be too limited to support meaningful risk adjustment or outcome analysis.

The MPSC Vice Chair explained that survival outcomes are evaluated using a Bayesian methodology. For programs with a small number of cases, this results in wider confidence intervals, reflecting greater uncertainty. However, because the cohorts are assessed over a 2.5-year period, the Scientific Registry of Transplant Recipients (SRTR) believes there will be sufficient data to support meaningful risk adjustment for the affected populations. They also noted that outcome thresholds have recently been adjusted. A program is now flagged for review only if there is a 50 percent probability that its odds ratio exceeds 2.25—significantly more lenient than previous standards. In practical terms, a program would need to have approximately three times the expected failure rate to trigger a review.

A member asked for clarification on how kidney-pancreas transplants, the only multi-organ transplant currently being monitored, are currently evaluated. Specifically, they asked whether these outcomes are treated as a distinct category or assessed within broader kidney transplant outcomes, and whether the kidney component is considered higher risk. An SRTR representative responded that both kidney and pancreas graft survival are evaluated separately within the kidney-pancreas category, and that these data are provided directly to the MPSC. They clarified that kidney-pancreas transplant outcomes are compared only against other kidney-pancreas programs—not against kidney-alone or pancreas-alone programs. Similarly, outcomes from liver-kidney transplants, for example, would not be compared to either liver-alone or kidney-alone results.

The Committee Vice Chair concluded by noting that the MPSC should consider how the proposed changes to multi-organ allocation policy may affect outcome evaluations. The Vice Chair of the MPSC confirmed that they will be working closely with the Multi-Organ Transplant Committee on this issue.

Next steps:

The project was recommended to the Executive Committee for approval.

3. Post-Implementation Review: Modify Data Submission Policies

The Committee received a presentation on the post-implementation monitoring report from the Vice Chair of the Data Advisory Committee (DAC).

Summary of discussion:

A member commented that it is good to see this data being monitored by the DAC and they appreciate being able to see the report.

Next steps:

A memo will be sent to the sponsoring committee summarizing the POC's discussion.

4. Summer 2025 Public Comment Preview

Staff shared the proposed projects being released for public comment Summer 2025.

Summary of discussion:

The Vice-Chair of the Organ Procurement Organization Committee (OPO) shared that their proposed project, *Review of Donation after Cardiac Death (DCD) Policies* will not be going out for the summer

cycle. They clarified that there were some changes made, and the Health Resources and Services Administration (HRSA) has sent a directive to the OPO Committee to add other elements. The OPO Committee made the decision to pull the project from this cycle to allow enough time to respond to the HRSA directive as well as make the necessary changes and ensure a complete review of the policies are conducted.

Staff asked the group if there are any particular projects they would like to review to please send that request their way.

Next steps:

Staff will assign proposals for review and send those out to the members ahead of the July 24 meeting.

Upcoming Meeting(s)

- July 24, 2025 - Teleconference

Attendance

- **Committee Members**
  - Ty Dunn
  - Dennis Lyu
  - Erika Lease
  - Heather Bastardi
  - Kelley Hitchman
  - Lisa Stocks
  - Lisa McElroy
  - Lori Markham
  - Lorrinda Gray-Davis
  - Neha Bansal
  - Oscar Serrano
  - Rachel Miller
  - Sanjay Kulkarni
  - Scott Lindberg
  - Shimul Shah
- **SRTR Representatives**
  - Allyson Hart
  - Jon Snyder
- **HRSA Representatives**
  - Brianna Doby
  - David Berick
  - Frank Holloman
- **UNOS Staff**
  - Lindsay Larkin
  - Cole Fox
  - Betsy Warnick
  - Alina Martinez
  - Carlos Martinez
  - Eric Messick
  - Houlder Hudgins
  - Kaitlin Swanner
  - Laura Schmitt
  - Sara Langham
  - Sharon Shepherd
  - Stryker-Ann Vosteen
  - Susan Tlusty