

**OPTN Policy Oversight Committee
Meeting Summary
July 24, 2025
Teleconference
Erika Lease, MD, Chair**

Introduction

The OPTN Policy Oversight Committee (“POC” or “the Committee”) met via teleconference on 07/24/2025 to discuss the following agenda items:

1. Welcome and updates
2. Summer 2025 Public Comment Proposal Review

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

1. Welcome and updates

The Chair updated the Committee regarding the status of public comment activities. They noted that in a prior meeting with the Human Resources and Services Administration (HRSA), there had been discussion about a delay in the public comment period from its originally scheduled dates. A representative from HRSA confirmed that an update on the public comment timeline would be available within the next week. They assured the Committee no significant delays are expected. The Chair also mentioned that the *Establish Expedited Placement for Hard-to-Place Kidneys* project has been removed from the public comment slate. This change was made at HRSA’s request, in light of a directive to examine out-of-sequence and other allocation-related issues.

Summary of discussion:

The Committee agreed to pause discussion on that item until the appropriate groups could review the directive. A member asked whether the delay of the public comment timeline will impact the regional meeting schedule. A representative from HRSA shared that it is possible the regional meetings slated for August will be moved to September to account for the changes to the timeline.

2. Summer 2025 Public Comment Proposal Review

The Committee reviewed the items slated for public comment to provide a recommendation to the OPTN Board of Directors to release projects for public comment.

Summary of discussion:

The Committee voted on the following items as a block:

Require Patient Notifications for Waitlist Status Change (Transplant Coordinators Committee)

2025 Histocompatibility HLA Table Update (Histocompatibility Committee)

Data Collection on Normothermic Regional Perfusion (NRP) and Machine Perfusion (Organ Procurement Organization Committee)

Require West Nile Virus Seasonal Testing for Donors (Ad Hoc Disease Transmission Advisory Committee)

Update and Improve Efficiency in Living Donor Data Collection (Living Donor Committee)

Establish Comprehensive Multi-Organ Allocation Policy (Ad Hoc Multi-Organ Transplantation Committee)

Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage (Heart Transplantation Committee)

The Committee voted 12 approve, 0 object, 0 abstain.

Require Patient Notifications for Waitlist Status Change (Transplant Coordinators Committee)

The proposal seeks to update OPTN *Policy 3.5: Patient Notification* to add a requirement related to patient activation and inactivation. The previous benefit score assigned by POC was 87 and the project was identified to align with the strategic plan goal of increasing transplant opportunities. The previous POC discussion noted strong support for the proposal particularly regarding transparency and patient access. Concerns were raised about the lack of data showing that notifications improve patient outcomes, the potential for increased administrative burden, and the risk of patients misinterpreting inactivation as a negative outcome. HRSA requested the POC further deliberate further on how this proposal might impact patients.

A member provided their insight, expressing strong support for the proposal, describing it as a low-cost initiative with potentially significant benefits, noting the possibility of increased patient engagement. They also commented that the policy might close a loophole where some transplant centers might inactivate patients without their knowledge, only to reactivate them later under a different attending physician. The Chair agreed with this assessment, also highlighting the proposals value in helping patients. Another member, also a patient representative, shared their personal perspective on the importance of the proposal. They observed that many patients they have spoken with were unaware of their inactive status, which caused significant stress and mental health challenges. Discovering they were inactive often led to confusion and frustration. They emphasized that knowing whether one is active or inactive provides clarity and empowerment.

2025 Histocompatibility HLA Table Update (Histocompatibility Committee)

The proposal seeks to update the HLA table referenced in OPTN *Policies 4.10* and *4.11*. The previous benefit score assigned by POC was 91 and the project was identified to align with the strategic plan goal of optimizing organ use.

A member noted that this proposal was part of the Histocompatibility Committee's annual review of HLA tables and commended the Histocompatibility Committee for providing clear rationale for the proposed and necessary updates to the table. They found no additional concerns that would require further public comment feedback. Another member echoed those remarks, emphasizing the proposal reflects the important maintenance work to keep policies align with current practices and technologies.

They also noted that while the number of affected cases may be small, the updates could help prevent inadvertent incompatible transplants.

Data Collection on Normothermic Regional Perfusion (NRP) and Machine Perfusion (Organ Procurement Organization Committee)

The proposal seeks to establish new data collection protocols for the use of NRP in organ procurement and machine perfusion in organ preservation and transport. The previous benefit score assigned was 69 and the project was identified to align with the strategic plan goal of enhancing OPTN efficiency.

Staff noted that HRSA had identified this proposal as potentially impacted by the NRP directive.

Member feedback indicated that the proposal clearly addressed its purpose, explained the rationale, and provided sufficient evidence for the proposed solution. A member voiced their strong support stating that data collection is essential for the transplant community and for patients. The Chair voiced their agreement, noting that while the NRP directive may raise ethical and safety concerns requiring separate data, the current proposal is focused on collecting clinical data to improve understanding and should therefore move forward. Another member affirmed the projects appropriateness and necessity given the increasing use of NRP and the need for monitoring.

Require West Nile Virus (WNV) Seasonal Testing for Donors (Ad Hoc Disease Transmission Advisory Committee)

The proposal seeks to require seasonal testing for WNV in donors and would update OPTN Policies 2.9 and 14.4 to mandate all deceased and living donor recovery hospitals conduct WNV testing between July 1 and October 31. The previous benefit score assigned was 53 and the project was not identified as aligning with any of the strategic plan goals.

A member shared their feedback that the proposal seemed common sense as many organ procurement organizations (OPOs) already conduct WNV testing. They did raise concerns about the supporting data, as it only included percentages of patients who died from encephalitis without providing the actual numbers. The member also suggested expanding the scope of community feedback to ask whether the proposed seasonal window is sufficient, noting that WNV is endemic in some regions earlier than July. Additionally, inconsistencies in the policy language were noted regarding when testing results must be available and how OPOs should report pending or incomplete results in the electronic notification system. The Vice Chair of the Ad Hoc Disease Transmission Advisory Committee (DTAC) clarified that the proposal is designed to align with CDC and FDA recommendations and that the July-October window represents a minimum requirement, not a restriction. They noted that OPOs are permitted to test outside of that range based on regional needs. They also noted that the main policy change would affect the living donor registration form while fields for the deceased donors would remain largely unchanged. They acknowledged the additional feedback and confirmed DTAC would consider the adjustments.

Update and Improve Efficiency in Living Donor Data Collection (Living Donor Committee)

The proposal aims to enhance data collection by gathering information on potential donors who do not proceed with donation and by transitioning long-term follow-up responsibilities to the Scientific Registry for Transplant Recipients (SRTR). The previous benefit score assigned by POC was 93 and the project was identified to align with the strategic plan goal of enhancing OPTN efficiency.

One member emphasized the importance and strong intent behind the proposal, commending the Living Donor Committee's efforts to engage a diverse group of stakeholders. They noted that while there are implementation challenges and uncertainties around resource requirements, opening the proposal up for public comment could help refine logistical strategies and inform feasibility. Another member,

also a patient representative, highlighted the significance of the proposal from the patient perspective. They stressed the importance of having reliable data to inform potential donors about long-term outcomes. They believed that better data transparency could encourage more individuals to become donors and strongly support implementation. Another member noted that the proposal is a response to an unmet need and appreciated the phased rollout, emphasizing the value of public comment feedback in improving the proposal and reducing the burden on data submitters. A different member, speaking as a non-directed living donor, advocated for long-term follow-up beyond the two-year standard. They noted the lack of clarity around post-donation monitoring can be unsettling for potential donors, stating that even partial data collection would be a significant improvement over current state.

The Vice Chair of the Living Donor Committee acknowledged the feedback and agreed that public comment would be especially valuable given the proposal's scope and goals, which include addressing barriers to living donation and improving long-term follow-up.

Establish Comprehensive Multi-Organ Allocation Policy (Ad Hoc Multi-Organ Transplantation Committee)

The proposal aims to standardize the order of priority across different organ match runs by incorporating multi-organ allocation tables into OPTN policy. The previous benefit score assigned was 81 and the project was identified to align with the strategic plan goal of Optimizing Organ Use.

A member acknowledged the complexity of the proposed algorithm, noting that its intricacy would make modeling impossible, and despite this, they supported moving the project forward to public comment as they believed in the importance of data collection and follow-up to monitor outcomes. Another member echoed the concerns, commending the Multi-Organ Transplantation (MOT) Committee for tackling the issue. From their OPO perspective, they highlighted there are risks of staff errors due to the complexity of multi-organ allocation and expressed hope that the system would allow for quick adjustments if problems arise. They emphasized that a single match run would be ideal, though that might not be feasible at this time. The Chair added their lung transplant program perspective, noting the challenges in listing and transplant multi-organ patients. They agreed with the need for flexibility and rapid response if issues emerge post-implementation.

Another member shared their pediatric specialist perspective, noting the added complexity for pediatric cases especially with kidney allocation metrics such as Kidney Donor Profile Index (KDPI). They expressed hope that post-implementation monitoring would help assess the impact on vulnerable populations over time.

The Chair of the MOT Committee agreed with the importance of post-implementation monitoring.

Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage (Heart Transplantation Committee)

This proposal, due to its emergency nature, has already been implemented and is now being released for retrospective public comment. The proposal updates the Heart Review Board guidance to include descriptions of circumstances and clinical factors under which pediatric reviewers should consider granting Status 1A exception requests. The change was prompted by a shortage of ventricular assistance devices (VADs) for small children and infants. Staff shared a draft benefit score of 83 and sought Committee input.

A member shared feedback that the proposal was concise and clearly outlined the purpose and rationale and was ready for public comment release. Another member, one who was involved with the development of the update, expressed their hope that the VAD shortage is temporary and emphasized the importance of monitoring and reassessing the guidance over time. The Heart Committee Vice Chair added that the guidance was intentionally written without naming specific devices, allowing for

flexibility as technologies and market conditions change. They stressed the unpredictability of shortages and the need for adaptable policy. The Committee confirmed the benefit score of 83 for this project.

Additional discussion

Staff sought any additional feedback from the Committee regarding the project benefit scores and whether the prioritization of the public comment slate felt appropriate or needed adjustment before being shared with the OPTN Executive Committee and the OPTN Board of Directors.

A member queried what prioritization would mean for each proposal, specifically those that are ranked lower. The Chair clarified that, at present, there is no direct consequence tied to a proposal's benefit score; however, they noted that growing awareness of budget constraints and the possibility that prioritization may influence future resource allocation. The member raised their concern about the NRP proposal being rated "high-cost, low-benefit," questioning how such a critical initiative could be considered low benefit. The Chair noted that the benefit scores are relative to other projects in the portfolio and are based on a scoring framework applied during initial evaluation. They emphasized that the "low benefit" label does not mean the project lacks value, simply that it had a lower score compared to others. Staff added that the benefit score was originally collected via survey in September 2024 and that Committee could choose to revisit and rescore any proposal if needed.

Another member strongly advocated for reevaluating the NRP proposal, noting that its impact on vulnerable populations and public trust in transplantation had been undervalued. They noted that both donors and recipients affected by NRP are inherently vulnerable and the proposal deserves a higher benefit score. One member echoed the comments, highlighting that much has changed in the NRP landscape since the original scoring, including federal-level developments. The Chair agreed and confirmed the Committee is open to reevaluating scores as projects evolve.

Staff committee to sending out a new survey to rescore the NRP proposal. Staff then queried if the Committee wanted to remove any proposals from the block prior to voting. Members confirmed to vote for the projects in a block.

The Committee voted 12 approve, 0 object, 0 abstain to recommend the projects to the OPTN Executive Committee for release for public comment.

Next steps:

Staff will send out a new survey to rescore the NRP proposal.¹

Upcoming Meeting(s)

- September 4, 2025 – Teleconference
- October 2, 2025 – Teleconference

¹ The POC was re-surveyed after the meeting and the adjusted benefit score for the *Data Collection on Normothermic Regional Perfusion (NRP) and Machine Perfusion* project is 90.

Attendance

- **Committee Members**
 - Ty Dunn
 - Dennis Lyu
 - Erika Lease
 - Heather Bastardi
 - Kelley Hitchman
 - Lisa Stocks
 - Lisa McElroy
 - Lori Markham
 - Lorrinda Gray-Davis
 - Neha Bansal
 - Rachel Miller
 - Sanjay Kulkarni
 - Cynthia Forland
 - Jennifer Prinz
 - Paige Porrett
 - Hannah Copeland
 - Aneesha Shetty
- **SRTR Representatives**
 - Allyson Hart
- **HRSA Representatives**
 - Stephanie Grosser
 - Ray Lynch
 - Brianna Doby
- **UNOS Staff**
 - Sara Langham
 - Jamie Panko
 - Lindsay Larkin
 - Carlos Martinez
 - Emily Ward
 - Sarah Roache
 - Kaitlin Swanner
 - Kevin Daub
 - Robert Hunter
 - Tamika Watkins
 - Susan Tlusty
 - Stryker-Ann Vosteen
 - Ethan Studenic
- **Other attendees**
 - John Magee