

## OPTN Executive Committee Meeting Summary

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### Meeting Information: Agenda and Attendees

Thursday, March 6, 2025 | 1:00–2:30 p.m. ET Location of Event: Zoom

#### Agenda

- Welcome and Announcements
- New Project Consideration
  - Pediatric Transplantation Committee: Standardize Lost to Follow-Up Reporting and Enhance Data Collection on Lost to Follow-up & Transfers of Care
  - Pancreas Transplantation Committee: Guidance on Improving Efficiency in Pancreas Transplantation
  - Kidney Transplantation Committee: Establish Expedited Placement Policy for Hard-to-Place Kidneys
- HRSA Directive on Allocating Organs out of Sequence Updates and Next Steps
- PAC/PALS Project Discussion
- Planning for Off Cycle Public Comment Period
  - NRP
  - HOPE Act
- Open Discussion
- Adjourn

#### Attendees

Attendee Name(s)	Affiliation
Emily Blumberg, Erika Demars, Richard Formica, Jen Lau, Macey Levan, Silas Norman, Lloyd Ratner, George Surratt, Andrea Tietjen	OPTN Board of Directors
Aitebureme Aigbe, Stephanie Grosser, Janelle Isley, Raymond Lynch, Chris McLaughlin	HRSA Representatives
George Barnette, Melanie Bartlett, Tennille Daniels, Jady Dunning, Karen Edwards, Emily Elstad, Christine Jones, Tessa Kieffer, Anthony LaBarrie, Mary Lavelle, James Montgomery, Laila Odeh, Rachel Shapiro, Christina Sledge, Lee Thompson	OPTN Board Support Staff
Roger Brown, Cole Fox, Kaitlin Swanner, Susan Tlusty, Stryker-Ann Vosteen	OPTN Operations Contractor Staff
Neha Bansal: Pediatric Transplantation Committee (Vice Chair) Jim Kim: Kidney Transplantation Committee (Chair) Jennifer Prinz: Policy Oversight Committee (Chair)	OPTN Committee Representatives
Rexanah Wyse Morrissette	OPTN Interim Executive Director

## Meeting Summary

### Welcome and Announcements

The Executive Committee (EC) meeting began once quorum was established.

### New Project Consideration

The Policy Oversight Committee (POC) chair shared an overview of the policy project process. For each new project, the POC evaluates projects prior to the presentation to the Executive Committee (EC), and completes a project form detailing the project's intent, purpose, and plan. If the project is approved, the sponsoring committee develops the full proposal. The EC later reviews and approves the project for public comment. The POC Chair explained the benefit scoring component, which creates a granular way to evaluate projects, and noted that projects included benefit and a fiscal year estimate cost for consideration.

The POC Chair shared presented 3 policy projects to the EC.

#### *Pediatric Transplantation Committee: Standardize Lost to Follow-Up Reporting and Enhance Data Collection on Lost to Follow-up & Transfers of Care*

The purpose of this project is to clarify the transplant program responsibilities for reporting, loss to follow up, and transfer of care, to create consistency within the data collection process; the project is sponsored by the Pediatric Transplantation Committee (PTC). This project would add to the policy definition and reporting criteria for loss to follow up and transfer of care. The POC chair stated that loss to follow up designation stops the generation of transplant recipients on follow-up forms, so there is a loss of critical data. Improving the understanding of barriers to access for post-transplant follow up care and age at transfer to adult care is of particular interest.

The Data Advisory Committee (DAC) endorsed this project, supported including adult transplant recipients, suggested considering patient perspectives and differences across all organs, and suggested exploring the utilization of the not seen option.

If the project is approved, the PTC and DAC will schedule a second meeting to review the detailed description of the proposed changes to the OPTN data prior to public comment release, for increased efficiency purposes. The total cost is slightly more than \$140,000 and the project score is 70. The POC Chair noted that the project comes out at a higher cost and lower benefit in the benefit versus cost plot quadrant. The POC Chair said there is good alignment with this project and the strategic plan, and the project aligns with the important initiatives for loss to follow up in the pediatric population. The key metrics are proportion of recipients that are reported as lost to follow up. The submitted reasons for the recipient loss of follow-up is a distribution of age at transfer. If approved, this would be expected to begin in June 2026. The POC fully supports the project and supports including adult recipients.

An EC member recommended including whether or not patients have English language skills as a data collection point.

EC Voting results: Approve: 8 Reject: 0

*Pancreas Transplantation Committee: Guidance on Improving Efficiency in Pancreas Transplantation*

The purpose of this project is to provide insight on better practices, promote efficiency and procurement, and increase utilization of the pancreas; the project is sponsored by the Pancreas Transplantation Committee. The project is aligned with optimizing organ use and the key metrics for the project are increasing the number of pancreas transplants and increasing the number of pancreas procurements. Upon its review, the POC determined that the project aligned well with the strategic plan for optimizing organ utilization. It addresses the declining pancreas transplant rights and the continuous distribution changes. The POC recommended collaborating with endocrine experts to enhance patient education, the referral process, and standardizing data collection.

The cost estimate was just under \$36,000 over fiscal year 2025 to 2026 with 19 months for this project. The project score overall was 64 with a low-cost low benefit score. If approved, the project would begin June 2026. The POC unanimously recommended moving this project forward to the EC.

EC members and HRSA raised concerns regarding whether a guidance document is effective and whether a policy would be a better option. The POC Chair and Pancreas Transplantation Committee Liaison explained that a guidance document is a relatively low-cost way to increase pancreas transplants in the community, and provides additional guidance on procurements as rates of pancreas transplants have been declining for the past several years. The proposed changes are not related to policy; rather, they are improvements in practices and training.

EC members made several suggestions, including asking medical societies to work on this, the OPTN working in conjunction with medical societies, and exploring policy as a solution.

EC voting results: Approve: 3 Reject: 5

The Chair will let the POC know that the project did not move forward, and will share the EC's feedback with the POC. One EC member reminded the group that a guidance document can be an intermediate step that works towards policy.

*Kidney Transplantation Committee: Establish Expedited Placement Policy for Hard-to-Place Kidneys*

The purpose of this project is to look at developing a nationally standardized and expedited allocation policy for hard-to-place kidneys that are at risk for non-use, and the policy would then be adapted for continuous distribution; the project is sponsored by the Kidney Transplantation Committee. This project aligned with the September 2023 OPTN Board resolution directing the KTC to consider expedited placement pathways for kidneys at risk for non-use and the impact on continuous distribution and allocation out of sequence. The policy would apply to all OPTN members engaged in kidney allocation.

The DAC declined to endorse the new opt-in data field at the February 10<sup>th</sup> DAC feedback meeting, and requested more information on how expedited offers will be defined and how the future policy would work. If the project is approved, the KTC and DAC would schedule a second meeting to review a more detailed description of the proposed changes to the OPTN data prior to public comment.

The cost estimate was just over \$500,000 over fiscal year 2025 to 2029. The project score was a high-cost high benefit score. The project is in alignment with optimizing organ use and the key metrics are

non-use rates for deceased kidney donors eligible for expedited placement and targets out of sequence challenges around deceased kidney donors eligible for expedited placement. The POC recommended moving this project forward to the EC.

HRSA stated this project should be reworked to at least reflect the comments in the critical comment and should be a part of the OPTN response. The EC clarified this is not a pause on the idea but rather a pause on the timing so that it harmonizes with other work that is being done. The KTC said uniformed messaging on project status and timing would be helpful. The POC chair asked if the proposal would fit into the overall picture if it had a quicker timeline and the EC clarified that there is a timeline issue and that everything must comply with NOTA, so the committee must get instructions from the EC. HRSA and the EC stated this could come back to the EC if it is reviewed and revised to be a part of the overall plan, in about a month.

EC voting results: Approve: 1 Reject: 2 Abstain: 5

The EC indicated the project was a good idea, if it was coming in addition to the larger initiative in the next month. However, they cannot approve a standalone project today as they are going to approve a package of projects in the next few months and approving one now could be irresponsible.

#### [HRSA Directive on Allocating Organs out of Sequence Updates and Next Steps](#)

The EC stated that the tasks coming out of the HRSA secretarial directive have been distributed among different committees. The EC went through Part A through D and gave a brief description of each part. Part A will be worked on by Member Quality (MQ) and the Membership & Professional Standards Committee (MPSC), the DAC, and the Operations and Safety Committee. Part B will be worked on by MQ. Part C will be worked on by the EC. Part D will be worked on by the IT and Data Analytics Group at UNOS. At the next meeting, the EC will develop a response for HRSA with a plan and timeline to meet requests. HRSA asked if the expedited kidney placement project would be incorporated into this and the EC said that if the KTC works under the context of NOTA it can be a part of the package.

#### [Patient Affairs Committee \(PAC\)/Patient Aware of Listing Status \(PALS\) Project Discussion](#)

In November 2024, the PAC voted on a resolution to develop a formal policy proposal which would ensure all patients are aware of their listing status. The PAC was asked to develop the policy first and then later work on a digital application, but there should be a sequence that the OPTN follows. The Transplant Coordinators Committee (TCC) and the Transplant Administrators Committee (TAC) were asked to put forward the policy addressing this topic, and were asked to involve the PAC through the policy development process.

HRSA stated this is an evolving policy and that changing patient status without their knowledge is a concern for patients. HRSA supported an approach that would provide a more holistic picture of an individual's status while they wait for an organ would be useful, which the EC supported. The EC will send a message saying they agree with this project and emphasize the importance of preserving the OPTN structure to move this work forward.

### Planning for Off Cycle Public Comment Period

Two high priority projects may require planning for off-cycle public comment: a project that aligns with the HIV Organ Policy Equity (HOPE) Act and a project that aligns with Normothermic Regional Perfusion (NRP) standards. Both projects will be reviewed by the POC on March 13<sup>th</sup>.

The EC asked HRSA if the NRP could still go out considering the plan for the larger project; HRSA stated that the NRP needs to be revisited in light of the overall plan and it should not be out on its own. The EC asserted that since it is a guidance document, it should not undo anything that will be responded to with the response to the Secretarial letter. An Operations and Safety Committee member noted that when the committee met on February 20<sup>th</sup>, they understood that there would be a pause and they did not vote to send this forward to the POC. The EC responded that the letter from the Secretary could then be given to the Operations and Safety Committee in the context that this may be one of multiple steps to be worked on. HRSA noted that putting out a guidance document in this setting could create confusion.

The POC is meeting on March 13<sup>th</sup> and is requesting the EC approve the projects for public comment between March 14<sup>th</sup> and 19<sup>th</sup> which would require an ad hoc meeting of this group. The alternative option is to approve this at the full Board meeting on March 20<sup>th</sup> which would delay the opening of the comment period by one day; the EC selected the latter option.

### Open Discussion

An EC member stated they have been informed by the community that a new policy called the “Revise Conditions for Access to the OPTN Computer Systems” is slated for implementation on March 27<sup>th</sup>. Some organizations that have used this system to place organs are going to lose access due to this policy, so the member asked if the group could look at unintended consequences and discuss them with the Network Operations Oversight Committee (NOOC). The EC confirmed that the policy can still move forward but a conversation with the NOOC Committee Chair is needed to discuss policy revisions to prevent endangering patients.