

**OPTN Policy Oversight Committee
Meeting Summary
September 12, 2024
Teleconference
Jennifer Prinz, BSN, MPH, Chair
Erika Lease, MD, Vice Chair**

Introduction

The OPTN Policy Oversight Committee (POC) met via teleconference on 09/12/2024 to discuss the following agenda items:

1. New Project: *Modify Lung Donor Testing Data Collection*
2. New Project: *Ethical Analysis of Possible Impacts Xenotransplantation on Human Allograft Organ Allocation*
3. New Project: *Machine Perfusion Data Collection*
4. Project Update: *Establish Comprehensive Multi-Organ Allocation Policy*
5. Strategic Plan Discussion
6. Post-Implementation Monitoring Review: *DAC Refusal Codes*

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

1. New Project: Modify Lung Donor Testing Data Collection

The Committee reviewed the following project: *Modify Lung Donor Testing Data Collection*.

Presentation Summary:

This proposal promotes efficiency of lung allocation by considering changes to OPTN data collection. This project is part of the overarching project to promote efficiency in lung allocation and in lung donor testing. Summary of Discussion:

Overall, members supported the project. POC members identified that it improves the ability to apply specific filters in selecting lung offers in upcoming cycles as well as allows for more efficient filtering of lung offers based on specific criteria.

Vote:

Does the Committee recommend approval of new project to Executive Committee?

16 yes, 0 no, 0 abstain

Next Steps:

The project will be reviewed by the Executive Committee for approval.

2. New Project: Ethical Analysis of Possible Impacts Xenotransplantation on Human Allograft Organ Allocation

The Committee reviewed the following project: *Ethical Analysis of Possible Impacts Xenotransplantation on Human Allograft Organ Allocation*.

Presentation Summary:

As xenotransplantation progresses as a potential therapy for organ failure, there are questions of how xenotransplantation will interface with the human allograft allocation system. This project aims to examine these considerations through an ethical analysis. **Summary of Discussion:**

Concerns were raised about the language used in the white paper, particularly the comparisons between xenotransplantation participants and living donors. Suggestions have been made to modify the language to avoid spreading misconceptions. The Vice Chair pointed out that discussions on xenotransplantation could guide future medical innovations. Another member raised questions about whether xenotransplantation should be considered a transplant and about OPTN's involvement in the matter.

Members also highlighted concerns about patient selection and education for xenotransplantation, suggesting that the ethics paper might be addressing questions too far in advance. Members discussed changing the title to focus on medical innovation more broadly. Overall, the members appreciated the complexity of the topic, balancing the need to be proactive in ethical discussions with the rapidly evolving nature of the field and potential public perceptions.

Vote:

Does the Committee recommend approval of new project to Executive Committee?

13 yes, 2 no, 0 abstain

Next Steps:

The project will be reviewed by the Executive Committee for approval.

3. New Project: *Machine Perfusion Data Collection*

The Committee reviewed the following project: *Machine Perfusion Data Collection*.

Presentation Summary:

This project aims to gather more detailed data on the use of machine perfusion and normothermic regional perfusion (NRP). Perfusion data is currently collected by Organ Procurement Organizations, transplant programs, device companies, and the OPTN. However, there is a lack of centralized data collection, and NRP data is limited within the OPTN system. Improved data collection will help the community better understand the impact on organ allocation/placement and patient outcomes.

Summary of Discussion:

The project's timeliness was emphasized by members, with one member suggesting not to underestimate the impact on vulnerable populations through increased organ utilization. They emphasized the importance of data collection for perfusion devices. Another member raised questions about the application to devices under clinical trials and potential barriers in data sharing between medical device companies.

A member asked about creating specific fields for each organ type, including NRP. A member of the Organ Procurement Organization (OPO) Committee confirmed that different data parameters would be created for each organ, with universal parameters for existing devices and the ability to add new ones as needed. The Chair asked about the impact on individual organ types and the risks of not pursuing this project. A member of the OPO Committee explained that the data could influence organ allocation, allowing for broader geographical distribution (e.g., sending a heart from California to New York). The data will help with retrospective reviews and potentially improve organ placement.

Vote:

Does the Committee recommend approval of new project to Executive Committee?

15 yes, 0 no, 0 abstain

Next Steps:

The project will be reviewed by the Executive Committee for approval.

4. Project Update: Establish Comprehensive Multi-Organ Allocation Policy

The Committee reviewed the following project update: *Establish Comprehensive Multi-Organ Allocation Policy*.

Presentation Summary:

The project was initially approved by the Policy Oversight Committee and the Executive Committee in October 2022. Initially, the focus of the project was on kidney multi organ transplant (MOT) allocation, but the scope now includes MOT allocation for all organs. The purpose of the update was to provide information on the broader scope of the project and updated resource estimates. The project aims to ensure fair access to transplants for both multi-organ and single-organ candidates and to streamline the allocation process when a donor has multiple organs available. The Committee's approach is to prioritize multi-organ transplants and single-organ candidates in different match runs by specifying the order in which OPOs process match runs. However, this will not alter the ranking order established for organ-specific policies.

Summary of Discussion:

A member commented about conflicts between multi-organ and single-organ allocations. For example, a patient with a MELD score of 40 who needs a liver might be overlooked in favor of a heart-liver allocation. Another member added that this issue has been discussed in the Liver Committee and has impacted multiple patients. Therefore, the member commented there is a need to monitor this data and determine the best approach. A member of the MOT Committee confirmed that the severity of patients' illness has been the primary factor used for allocation, with other considerations including proximity to the donor, mortality rate on the waitlist, and survival rate after transplant. A member of the MOT Committee reported that the Values Prioritization Exercise (VPE) showed strong consensus on prioritizing medical urgency. Members discussed the projected timeline for the project. Staff commented that the estimated timeline for the project is contingent on final Committee decisions which may impact the complexity of implementation.

Vote:

Does the Committee recommend approval of the project updates to Executive Committee?

13 yes, 0 no, 0 abstain

Next Steps:

The project will be reviewed by the Executive Committee for review.

5. Strategic Plan Discussion

The Committee reviewed the 2024-2027 Strategic Plan goals and objectives along with the active project portfolio to confirm strategic plan alignment.

Presentation Summary:

The OPTN Strategic Plan is a roadmap to help prioritize major initiatives of the OPTN over a three-year period. It was approved by the OPTN Board of Directors in June 2024 and implemented July 2024. The plan is not intended to be an exhaustive list of the OPTN's work or focus areas. It includes flexibility for the Board to add or redirect as needed to capitalize on emerging opportunities.

Staff conducted an initial assessment of Strategic Plan goal alignment for active projects (projects that have been approved by the Executive Committee).

POC members then reviewed project intent and Strategic Plan impact statements to confirm alignment.

Summary of Discussion:

One member mentioned having trouble distinguishing between different Strategic Plan goals when evaluating policies. A staff member commented that even though projects may apply to multiple goals, there should be one Strategic Plan goal identified the project primarily aligns with. Lastly, a member expressed concern about potential conflicts arising from efforts to optimize organ allocation, particularly regarding hard-to-place organs, international considerations, and living donors. They specifically mentioned ethical challenges related to allocating organs out of sequence.

The POC confirmed the following projects aligned with the following Strategic Plan goals:

Goal 1: Increase Opportunities for Transplants

- Management of International Living Donors in the U.S.
- Promote Efficiency of Lung Donor Testing

Goal 2: Optimize Organ Use

- Ethical Analysis of Allocating Organs Out of Sequence
- Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS
- Re-evaluation of Deceased Donor Testing Requirements
- Establish Comprehensive Multi-Organ Allocation Policy
- Update Criteria for Post-Transplant Graft Survival and Offer Acceptance Metrics
- Continuous Distribution of Kidneys
- Continuous Distribution of Pancreata
- Continuous Distribution of Livers & Intestines
- Continuous Distribution of Hearts

Goal 3: Enhance OPTN Efficiency

- Requirements for Communicating Post-Transplant Disease
- Update and Improve Efficiency in Living Donor Data Collection
- Machine Perfusion Data Collection

Goal 4: Support OPTN Modernization Initiatives

- Revise Conditions for Access to the OPTN Computer System and Reporting Privacy Incidents involving OPTN Data

Aligns with Other Important Initiative

- Escalation of Status for Time on Left Ventricular Assist Device
- Monitor Ongoing eGFR Modification Policy Requirements
- Ethical Analysis of Possible Impacts Xenotransplantation on Human Allograft Organ Allocation

- Review and Update OPTN Histocompatibility Committee Guidance and Policy with Current Practice
- Reduce HLA Critical Discrepancies and Require Reporting to the OPTN

Next Steps:

POC feedback will be summarized and reported to the Executive Committee.

6. Post-Implementation Monitoring Review: DAC Refusal Codes

The Committee reviewed a summary of the Data Advisory Committee's assessment of the post-implementation monitoring report for the *DAC Refusal Codes* project.

Presentation Summary:

On December 2, 2021, the OPTN made changes to the options listed in the dropdowns for organ offer refusal codes in response to feedback from the Data Advisory Committee. It was found that "Donor age or quality" accounted for the majority of refusals entered by centers for organ offer refusals. The lack of specificity in refusal codes made it difficult to understand the reasons behind organ refusal using the data. The goal was to improve donor and recipient matching by enhancing the refusal reason data for quality improvement, retrospective reviews, and real-time decision-making. This was done by providing more relevant and specific options. The Data Advisory Committee revised the options to make them more relevant, discrete, and mutually exclusive, in order to collect more actionable data. Additionally, a second refusal code field was provided to capture more than one response when multiple factors drive a refusal decision. Overall, monitoring results suggest that the project achieved its outcomes. However, there are still opportunities for potential improvements.

Summary of Discussion:

The Vice Chair expressed concern about potential data skew towards kidney transplants and asked if the committee plans to examine the data by organ type. They mentioned that size and donation after circulatory death (DCD) code 717 are the only other codes they use. A member of the Data Advisory Committee confirmed that the data is not organ-specific and that they have data for all organs, noting that changes occur differently across organ types. Another member commented on the progress made in data collection and analysis, advising on the importance of considering end-users and human factor engineering, cautioning against having too many options. A suggestion was made to focus on creating a manageable number of categories with relevant data points. A member of the Data Advisory Committee agreed with the members' points, emphasizing the need to avoid being overly specific in cases where action cannot be taken.

Next Steps:

The POC's comments will be summarized in a memo for the Data Advisory Committee's consideration.

Upcoming Meeting(s)

- October 10, 2024 Teleconference

Attendance

- **Committee Members**
 - Erika Lease
 - Dennis Lyu
 - Cynthia Foreland
 - Hannah Copeland
 - Heather Bastardi
 - Jason Huff
 - Jennifer Prinz
 - Kelley Hitchman
 - Lisa McElroy
 - Neha Bansal
 - Paige Porrett
 - Rachel Miller
 - Sanjay Kulkarni
 - Shimul Shah
 - Steven Potter
 - Ty Dunn
 - Lisa Stocks
- **SRTR Representatives**
 - Allyson Hart
- **HRSA Representatives**
 - Adrianna Alvarez
 - Steven Keenan
 - Marilyn Levi
 - Shannon Dunne
- **UNOS Staff**
 - Lindsay Larkin
 - Viktoria Filatova
 - Cole Fox
 - Kaitlin Swanner
 - Kimberly Uccellini
 - Eric Messick
 - Kelley Poff
 - Kevin Daub
 - Houlder Hudgins
 - James Alcorn
 - Janis Rosenberg
 - Lloyd Board
 - Sarah Roache
 - Rebecca Goff
 - Robert Hunter
- **Guests**
 - Jesse Schold
 - PJ Geraghty
 - Zoe Stewart Lewis