

OPTN Policy Oversight Committee

Meeting Summary

April 11, 2024

Conference Call

Jennifer Prinz, BSN, MPH, Chair

Erika Lease, MD, Vice Chair

Introduction

The OPTN Policy Oversight Committee (the Committee) met via Cisco WebEx teleconference on 04/11/2024 to discuss the following agenda items:

1. New Project: Ethical Analysis of Allocating Organs Out of Sequence
2. New Project: Reduce HLA Critical Discrepancies and Require Reporting to the OPTN

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

1. New Project: Ethical Analysis of Allocating Organs Out of Sequence

The Committee reviewed the following project: *Ethical Analysis of Allocating Organs Out of Sequence*.

Presentation Summary:

The purpose of the project is to explore the ethical underpinnings of rescue pathways and associated implications for appropriate use. The white paper will analyze rescue pathways, with the balance of utility, autonomy, respect for persons, and equity in mind.

Strategic Goals: increase the number of transplants and increase equitable access to transplants. Efficiency relies on trust in the system, and by identifying and analyzing the ethical underpinnings of rescue pathways, this paper would increase trust and transparency, which then may increase the number of transplants. This project would explore how allocation out of sequence impacts equitable access for waitlisted candidates.

The paper is expected to be released for public comment in the January 2025 cycle. The collaborating committees would include the Kidney Committee, Organ Procurement Organization Committee, Patient Affairs Committee, and Membership & Professional Standards Committee.

Summary of Discussion:

Multiple members confirmed that the timing is appropriate for a white paper analyzing the ethical considerations around out-of-sequence/expedited organ offers and "rescue pathways" aimed at preventing organ discard.

Members agreed that out-of-sequence offers are a prominent issue currently, with some organ procurement organizations deviating from standard match runs, so having formal discussions and analysis is timely. Members commented that broader organ sharing has contributed to logistical delays that may necessitate expedited placement pathways to prevent non-utilization of organs. A member advised that there is a need for more transparency, consistency, and guardrails around when and how these expedited pathways are used across organ procurement organizations. Members suggested the white paper should aim to provide an ethical foundation and identify appropriate circumstances for expedited placement, rather than vindicate or condemn current practices.

Members noted that it is important to balance the imperative of organ utilization with fairness in allocation and patient autonomy. The analysis should examine geographic factors that may lead to some centers receiving more expedited offers.

Overall, members felt that thoroughly exploring the ethics around this issue now, before proposing any specific policy changes, is valuable and well-timed given the increasing prominence of expedited pathways used to prevent discard amid the broader sharing system. The key will be providing a rigorous analysis that can guide more transparent and consistent practices.

Vote:

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

13 yes, 1 no, 0 abstention

Next steps:

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

2. New Project: Reduce HLA Critical Discrepancies and Require Reporting to the OPTN

The Committee reviewed the following project: *Reduce HLA Critical Discrepancies and Require Reporting to the OPTN.*

Presentation Summary:

The strategic goal is promoting living donor and transplant recipient safety. The project purpose is to require reporting of HLA critical discrepancies to the OPTN as well as provide guidance on reducing HLA critical discrepancies. It would allow for additional review to determine if any quality steps, such as a Root Cause Analysis (RCA), are required to improve laboratory performance. Data on causes of HLA critical discrepancies is also important for informing future policy development.

Key Metrics:

- The total number of HLA critical discrepancies
- The distribution of HLA critical discrepancies across different histocompatibility labs

Rationale:

- This project is intended to decrease total HLA critical discrepancies by dissemination of best practices and increased accountability and quality review to determine causes of HLA critical discrepancies.

A proposal is expected to be released for Public Comment in the July 2024 cycle. The collaborating committee would be the Membership & Professional Standards Committee.

Summary of Discussion:

A member noted that while this project aligns with the 2024-2027 strategic plan, it is not the highest priority since the number of critical HLA discrepancies is relatively small (40-60 reports per year across HLA labs). However, tracking and trending these discrepancies is important for safety. It raises the point that the real goal may not be to immediately reduce discrepancies, but first to increase the identification and reporting of discrepancies that occur, so they can be analyzed and addressed. Another member suggested the title may be misleading. The Histocompatibility Committee Chair provided clarity that discrepancies can be caught at various points - during allocation review, after transplant when re-typing occurs, or suspected transcription errors. The proposal aims to collect more granular data on root causes.

The same member also raised concerns that the proposal combines different types of discrepancies (clerical errors vs. resolution level issues) which may require different strategies to address. They suggested adding additional collaborating committees like Kidney, Heart, etc. The Histocompatibility Committee Chair acknowledged that they want to first understand where/when in the process most discrepancies occur before developing targeted guidance and policies. All organ groups are stakeholders. The key takeaway is that while the intent to track HLA discrepancies aligns with strategic priorities, the proposal may need to be refined. There is a need to clarify if the immediate goal is increasing identification/reporting versus directly reducing discrepancies at this stage. As well as potentially separate categories of discrepancies that have distinct root causes and remediation strategies.

Vote:

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

13 yes, 1 no, 0 abstention

Next steps:

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

Upcoming Meeting(s)

- **May 9, 2024 – Teleconference**
- **June 13, 2024 - Teleconference**

Attendance

- **Committee Members**
 - Jennifer Prinz
 - Lisa Stocks
 - Rachel Engen
 - Kim Koontz
 - Nicole Turgeon
 - Christine Brenner
 - Scott Lindberg
 - JD Menteer
 - Lori Markham
 - Stevan Gonzalez
 - Ty Dunn
 - Peter Stock
 - Jesse Schold
 - Sanjay Kulkarni Shimul Shah
- **HRSA Representatives**
 - Shannon Dunne
 - Shelley Grant
- **SRTR Representatives**
 - Ajay Israni
- **UNOS Staff**
 - James Alcorn
 - Kaitlin Swanner
 - Jamie Panko
 - Susan Tlusty
 - Lindsay Larkin
 - Viktoria Filatova
 - Cole Fox
 - Kim Uccellini
 - Kieran McMahon
 - Laura Schmitt
 - Sarah Roache
 - Shandie Covington
 - Tamika Watkins
 - Courtney Jett
 - Roger Brown
- **Other**
 - John Lunz