

OPTN Operations and Safety Committee

Meeting Summary

April 24, 2025

Conference Call

Kim Koontz, MPH, Chair

Steven Potter, MD, Vice Chair

Introduction

The OPTN Operations and Safety Committee (the Committee) met via WebEx teleconference on 04/24/2025 to discuss the following agenda items:

1. Welcome
2. Updates and Next Steps: Project Directives
3. Project Update and Next Steps: Re-evaluation of Deceased Donor Testing Requirements
4. Open Forum
5. Closing Remarks/Adjourn

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

1. Welcome

The Chair welcomed the members and reviewed the agenda for the meeting.

2. Updates and Next Steps: Project Directives

The Committee received updates on directives regarding normothermic regional perfusion (NRP) and allocation out of sequence (AOOS).

Presentation summary:

Normothermic regional perfusion project timeline:

- September 26: Executive Committee directive for Committee to establish requirements for standardized practice in the use of NRP
- October 24 and November 7: Committee met and developed recommendations for consideration (policy, guidance, data collection)
- December 2: Board of Directors meeting
 - Report to Board submitted summarizing the Committee's recommendations
- December 12: Report to Executive Committee
 - Recommendation for OSC to move forward with a guidance document
- January 23 – February 22: Discussion and development of guidance document
- February 27: Request received from HRSA to pause voting on NRP guidance document
- March 5: HRSA response to critical comment received¹
 - OPTN response is being developed; to be submitted by April 30

Allocation out of sequence:

¹ <https://optn.transplant.hrsa.gov/media/uh2bcmx/critical-comment-to-optn-5march2025-nrp.pdf>.

- March Committee meeting was replaced with workgroup meetings to discuss the following portions from the HRSA response to the AOOS critical comment:²
 - A.3: Develop a proposed OPTN policy and associated definition to describe “batched organ offers”
 - A.4: Develop a proposed OPTN policy and associated definition for the “offer” of an organ by an OPO to a transplant center
 - A.5: Develop a proposed OPTN policy and associated definition to describe acceptable modalities and associated content of an organ offer made by an OPO to a transplant patient at a transplant center.
- OPTN response to AOOS was submitted March 31

Summary of discussion:

No decisions were made.

NRP

There were no questions or comments.

AOOS

A member asked if the current multi-organ allocation work falls into the “order of allocation criteria” at all. Staff noted there is potential overlap across policy development work that is in progress and work that may proceed under the directive, and the Ad Hoc Multi-Organ Transplantation (MOT) Committee is aiming to put out a public comment proposal during the summer 2025 public comment period.

Next steps:

The Committee will be updated once more information is available.

3. Project Update and Next Steps: Re-evaluation of Deceased Donor Testing Requirements

The Committee reviewed progress to date on the project to re-evaluate deceased donor testing requirements and discussed next steps.

Presentation summary:

The purpose of the project is to re-evaluate policies related to donor testing requirements to determine if any testing requirements are outdated or no longer relevant, or if other modifications to policy are needed:

- Deceased Donor General Risk Assessment (Policy 2.8)
- Deceased Donor Infectious Disease Testing (Policy 2.9)
- Additional Deceased Donor Testing (Policy 2.10)
- Required information for deceased kidney, liver, heart, and pancreas donors (Policies 2.11 A, B, C, and E)

The project does not include reviewing requirements for deceased lung donors as that was addressed via a separate project sponsored by the OPTN Lung Transplantation Committee.³ In addition to policy changes, the project includes proposed changes to OPTN guidance. The Workgroup developing the

² <https://optn.transplant.hrsa.gov/media/km3fskz1/hrsa-directive-to-optn-on-aos-022125.pdf>.

³ “Promote Efficiency of Lung Donor Testing,” OPTN, Policy Notice, https://optn.transplant.hrsa.gov/media/w5ifdhv/lung_promote-efficiency-of-lung-donor-testing--dec2024_pn.pdf.

recommendations considered incorporating system changes to indicate if blood draws required for blood type determination were performed pre- or post-transfusion, but decided to defer those changes to the OPTN Histocompatibility Committee as part of a project to re-evaluate *OPTN Policy 2.6 Deceased Donor Blood Type Determination*.

Summary of discussion:

No decisions were made.

There were no questions or comments.

Next steps:

The Committee will review the final recommendations from the Workgroup at an upcoming meeting.

4. Open Forum

There were no open forum requests for this meeting.

5. Closing Remarks/Adjourn

The Committee reviewed the dates of the upcoming meetings.

Upcoming Meetings

- May 22, 2025 (Teleconference)
- June 26, 2025 (Teleconference)

Attendance

- **Committee Members**
 - Kim Koontz, Chair
 - Steven Potter, Vice Chair
 - Amanda Bailey
 - Anja DiCesaro
 - Kaitlyn Fitzgerald
 - Laura Huckestein
 - Anne Krueger
 - Elizabeth Shipman
 - Jenn Smith
 - Norihisa Shigemura
- **UNOS Staff**
 - Betsy Gans
 - Chelsea Hawkins
 - Sharon Shephard
 - Kaitlin Swanner
 - Susan Tlusty
 - Niyati Upadhyay
 - Joann White