

# Meeting Summary

# OPTN Operations and Safety Committee Meeting Summary June 26, 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 06/26/2025 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. Project Update: Donation after Circulatory Death (DCD) Policy Review Project
- 5. Review and Discussion: Organ Data Collection Logistics Evaluation One Year Monitoring Report
- 6. Open Forum
- 7. 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. Contractor staff reminded members to complete their annual volunteer education and attestation requirements.

#### 2. Updates and Next Steps: Project Directives

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

#### Presentation summary:

AOOS: The OPTN submitted operational and analytic definitions of AOOS that were approved by HRSA; related correspondence is posted on the OPTN website

- Operational definition: "AOOS is when an organ is offered or accepted or transplanted into a transplant candidate or potential transplant recipient (PTR) that deviates from the match sequence and is not consistent with OPTN policy
- Analytic definition:
  - AOOS is identifiable using the following bypass codes:
    - 861 (Operational OPO)
    - 862 (Donor medical urgency)
    - 863 (Offer not made due to expedited placement attempt)
    - 887 (Not Offered expedited placement)
    - 799 (Other, specify)
  - Proposed that the presence of <u>one or more of these bypass codes</u> be used to identify instances of AOOS

NRP: No new updates

# **Summary of discussion:**

No decisions were made.

#### **A00S**

The Chair asked about the web page that will be developed for monitoring and how input will be provided for that. Contractor staff said there are ongoing discussions with the Health Resources and Services Administration (HRSA) on how to complete that work.

A member asked if there is any discussion on assessing what leads to AOOS, the impact of late declines, and other scenarios that put organs at risk. The member noted that AOOS is a reaction to a broader problem. Focusing on AOOS and not the broader issue of late declines and inadequate offer reviews by transplant programs is not looking at the full picture.

The Chair said that AOOS is predominately for abdominal organs and suggested studies on how well programs are utilizing their offer filters and the associated impacts on allocation. For example, these programs may get bypassed at a higher rate because they are more likely to decline organs.

The Vice Chair said that as AOOS approaches 38%, one would expect to see non-use rates go down, which is not necessarily the case. The Vice Chair recommended that HRSA consider non-use. The Vice Chair said for a lot of organ procurement organizations (OPOs), the AOOS is not in response to late turndowns but reflects OPOs leaping to AOOS early in the allocation process.

A member asked about the OPTN Expeditious Task Force (Task Force) dedicated to expedited allocation. Contractor staff noted that the Task Force was paused due to resource constraints.

A member asked about the intent of the directive work and whether the focus is on solving the underlying problems. Contractor staff said those questions came up in earlier workgroup discussions sponsored by the Committee and the contractor is awaiting further direction from HRSA based on their review of the plan developed by the workgroup.

#### NRP

There were no questions or comments.

#### 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 Workgroup met on June 18 to cross reference policy and system requirements. The Workgroup supported aligning policy requirements with system requirements. During the next meeting, the Workgroup will specify what tests should be required for evaluation (OPTN Policy 2.8) or for organ offer to be sent (OPTN Policies 2.11 A, B, C, and E).

#### 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. Project Update: Donation after Circulatory Death (DCD) Policy Review Project

The Committee received an update on the DCD Policy Review Project, sponsored by the OPTN Organ Procurement Organization Committee with participation from members of the Operations and Safety Committee.

#### Presentation summary:

The OPO Committee previously voted to send the DCD Policy Review proposal out for public comment but subsequently decided on their June 12 call to hold this proposal due to a new directive from HRSA calling for further changes to DCD policy.

#### Summary of discussion:

No decisions were made.

A member asked for more information regarding the focus of the directive. Contractor staff described the main requirements of the directive:

- The process by which a "pause" in procurement efforts can be undertaken if there is concern for unrecognized neurological improvement or potential for a patient to experience pain in the act of procuring organs
- 2. Requirements for family information about DCD organ procurement to be provided at the time of organ donation authorization
- 3. An addition to OPTN Policy 2.2 that describes the OPO's responsibility to ensure that the patient family, hospital staff, transplant center staff, and third party procurement and preservation staff are empowered to call for a "pause" on procurement efforts if they believe the patient is experiencing increased neurological function or is at risk of experiencing pain
- 4. An addition to OPTN Policy 2.2 that describes the OPO's responsibility to ensure accuracy in neurological assessment and appropriate neurological re-assessments

Contractor staff requested recommendations for volunteers who may be well suited to participate in the policy development.

# Next steps:

The Committee will receive a copy of the directive following the meeting.

# 5. Review and Discussion: Organ Data Collection Logistics Evaluation One Year Monitoring Report

The Committee reviewed the one-year monitoring report for the *Organ Data Collection Logistics Evaluation* project.

#### Presentation summary:

• Among the removed elements from DDR forms, "Other/Specify" type of liver perfusion made up about 8.6% of all types during the pre-policy period.

- With the removal of "Other/Specify" from type of liver machine perfusion, there was an increase in normothermic liver perfusion by 10% post-policy.
- For most organs, the "No candidate on the match run" reason, which was added to the DDR upon policy implementation, made up less than 4% of reasons the organ was not recovered
  - However, a larger proportion of intestines reported non-recovery due to "No candidate on the match run"
- The added organ check-in time and transplant time align well together.
  - Median organ check-in time was about half an hour before median transplant time which was about noon

# **Summary of discussion:**

No decisions were made.

There were no questions or discussion.

# 6. Open Forum

There were no open forum requests for this meeting.

# 7. Closing Remarks/Adjourn

The Committee reviewed the date for the next committee meeting.

# **Upcoming Meeting**

• July 24, 2025 (Teleconference)

#### Attendance

# • Committee Members

- o Kim Koontz, Chair
- o Steven Potter, Vice Chair
- o Amanda Bailey
- o Bridget Dewees
- o Anja DiCesaro
- o Kaitlyn Fitzgerald
- o Mony Fraer
- o Laura Huckestein
- o Sarah Koohmaraie
- o Anne Krueger
- o Annemarie Lucas
- o Megan Roberts
- o Norihisa Shigemura
- o Elizabeth Shipman
- o Jennifer Smith
- o Jillian Wojtowicz

# UNOS Staff

- o Chelsea Hawkins
- o Robert Hunter
- o Laura Schmitt
- o Erin Schnellinger
- o Kaitlin Swanner
- Niyati Upadhyay
- o Joann White