OPTN Operations and Safety Committee
Meeting Summary
May 22, 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 05/22/2025 to discuss the following agenda items:

1. Welcome
2. Updates and Next Steps: Project Directives
3. Review and Discussion: Develop Competencies for Qualified Health Professionals (QHPs) (Membership and Professional Standards Committee (MPSC) Project Referral)
4. Project Update and Next Steps: Re-evaluation of Deceased Donor Testing Requirements
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:

NRP:

- OPTN response was submitted April 30th [1]
- Awaiting further direction on next steps from the Health Resources and Services Administration (HRSA)

AOOS:

- OPTN response was submitted March 31st [2]
- Initial response from HRSA and directive received May 13th (no action tasked to the Committee at this time)[3]
- Awaiting further direction on next steps from HRSA

[1] https://optn.transplant.hrsa.gov/media/kziehz1t/optn-nrp-directive-reponse-04302025.pdf
[2] https://optn.transplant.hrsa.gov/media/uk4l0bh5/optn-response-hrsa-aoos-directive_03312025-508.pdf
[3] https://optn.transplant.hrsa.gov/media/sj4ligfb/aoos-initial-response-optn-05132025_508.pdf

Summary of discussion:

No decisions were made.

NRP

There were no questions or comments.

AOOS

There were no questions or comments.

Next steps:

The Committee will be updated once more information is available.

3. Review and Discussion: Develop Competencies for Qualified Health Professionals (QHPs) (Membership and Professional Standards Committee (MPSC) Project Referral)

The Committee reviewed and discussed next steps for a proposed project referral from the MPSC focused on developing competencies for QHPs.

Presentation summary:

Project Overview

Background

- OPTN Policy defines QHP as "a person who is qualified to perform blood type reporting or verification requirements as defined in the OPO, transplant hospital, or recovery hospital written protocol."
- MPSC has noted variation in protocols; concern these protocols may be insufficient in providing appropriate training and guidance to ensure that blood typing reporting and verification is done safely and accurately

Purpose/Proposal:

- Develop competencies for QHPs

Committee leadership feedback:

- Additional clarity needed of project scope/problem
    - Additional information is needed to determine root cause of issue (root cause analysis)
- Concern/question regarding responsibility/oversight of ABO education
    - Many labs are external labs and hospitals providing this service
- Consideration of other priorities OSC is currently working to address

The Histocompatibility (Histo) Committee were named co-sponsors for this project. Histo Committee leadership reviewed the project referral and voiced similar feedback and declined project due to lack of clarity on what the goal/actionable intervention would be.

Summary of discussion:

No decisions were made.

The Committee Chair added that in addition to the feedback shared, there was also similar sentiment on concern for regulatory requirements. The labs that are doing ABO testing have a regulatory body that they are accountable to and it was believed that this project could potentially result in some misalignment to these regulatory bodies the labs are already accountable to.

A member voiced agreement with Committee leadership's feedback and added with consideration of other regulating bodies to these labs, this project seems to be outside the scope of the OPTN.

The Committee concluded to not move forward with this project referral.

Next steps:

The Committee's discussion and recommendation will be provided to the MPSC.

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

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.[4] In addition to policy changes, the project includes proposed changes to OPTN guidance. The Workgroup developing the 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*.

Progress to date:

The Workgroup reviewed policies and provided recommendations (as applicable) that included:

- Policy modifications
- Updates to guidance (Guidance on Requested Deceased Donor Information, 2018)

April 16th and May 21st meetings: Workgroup reviewed and finalized policy and guidance recommendations

The Workgroup will have additional discussions to further clarify recommendations and cross referencing policy requirements and requirements in the OPTN Donor Data and Matching System.

Summary of discussion:

No decisions were made.

[4] "Promote Efficiency of Lung Donor Testing," OPTN, Policy Notice, https://optn.transplant.hrsa.gov/media/w5iffdhv/lung_promote-efficiency-of-lung-donor-testing-_-dec2024_pn.pdf.

There were no questions or comments.

Next steps:

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

5. Open Forum

There were no open forum requests for this meeting.

6. Closing Remarks/Adjourn

A member mentioned that at their OPO had a recent partial heart transplant and conferred with the OPTN Contractor on coding the disposition. The member asked where the OPTN was in general with reviewing partial heart transplants and if there is a plan to incorporate this into OPTN for allocation.

The Committee Chair clarified that the Committee had discussions on this topic last year with a presentation led by a Food and Drug Administration (FDA) representative and included representation from the OPTN Heart Transplantation Committee. It was concluded that there would not be guidance from the OPTN as the OPTN does not regulate partial hearts. Partial hearts is under the regulation of the FDA, where guidance is provided.

A member added that as a past member of the vascular composite allograft (VCA) Committee, partial hearts seems to be similar to VCA and the processes that would be done for those procedures and suggested further discussion may be needed. The Committee Chair commented that there were similar discussions in the past with the Committee, but the FDA was clear that partial hearts fell under their oversight. When it was discussed on possibly having guidance from the OPTN, it was clarified that there was guidance available through the FDA that should be followed and that partial hearts meets the definition of a tissue, not an organ.

The member continued by stating that from the recipient side, there is no allocation except for word of mouth to know what recipients are listed. From a patient perspective, there is a disadvantage with this process. The Committee Chair stated that there are some subject matter experts (SMEs) who their OPO works with in operationalizing these processes further and will follow up with additional information.

Another member commented that from their OPO, they have performed a partial heart as well and it also raised this question on allocation processes and how to prioritize if there are multiple candidates. From an OPO perspective, it would be helpful for guidance from the OPTN but understood the decisions made based on the previous discussions.

The Committee Vice Chair stated that for partial heart, for all intents and purposes, it is an organ transplant, just not the whole organ. The Committee Vice Chair voiced concern of this becoming an increasing problem with the progression of potential stem cell transplantation and tissue transplantation as a whole. The FDA rubric seems confusing and it is the hope that in the future this may be discussed/addressed further. A member agreed with this and commented with their knowledge of VCA there has been a struggle in understanding the difference.

The Committee reviewed the dates of the upcoming meetings. There were no additional comments or questions. The meeting was adjourned.

Upcoming Meetings

- June 26, 2025 (Teleconference)

Attendance

- **Committee Members**
  - Kim Koontz, Chair
  - Steven Potter, Vice Chair
  - Annemarie Lucas
  - Elizabeth Shipman
  - Jillian Wojtowicz
  - Kaitlyn Fitzgerald
  - Sarah Koohmaraie
  - Norihisa Shigemura
  - Mony Fraer
- **UNOS Staff**
  - Betsy Gans
  - Joann White
  - Kaitlin Swanner
  - Laura Schmitt
  - Niyati Upadhyay
  - Susan Tlusty
- Guests
  - Ray Lynch