

OPTN Operations and Safety Committee

Meeting Summary

February 27, 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 2/27/2025 to discuss the following agenda items:

1. Open Forum
2. Update: Standardize Practice in the use of Normothermic Regional Perfusion (NRP) in Organ Procurement Guidance Document
3. Public Comment Presentation: Modify Lung Donor Data Collection
4. Public Comment Presentation: Establish Comprehensive Multi-Organ Allocation Policy

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

1. Open Forum

The Committee received an open forum request. The speaker joined the call to provide their feedback on the Committee's Normothermic Regional Perfusion (NRP) guidance document.

Summary of discussion:

The speaker provided feedback on the Committee's Normothermic Regional Perfusion (NRP) guidance document. The speaker voiced concern on addressing processes related to NRP as it pertains to steps made to avoid cerebral reperfusion. The Committee was urged to consider restricting NRP to controlled studies until further information is provided and the community can identify the best approach to ensuring cerebral reperfusion does not occur.

The Committee Chair thanked the speaker for their feedback which the Committee will take into consideration. There were no questions or additional comments.

2. Update: Standardize Practice in the use of Normothermic Regional Perfusion (NRP) in Organ Procurement Guidance Document

The Committee was provided an update on the Standardize Practice in the use of Normothermic Regional Perfusion (NRP) in Organ Procurement Guidance Document.

Summary of discussion:

The Committee was informed of a request from the Health Resources and Services Administration (HRSA) to pause the vote on the NRP guidance document. This pause is to allow the opportunity to review additional information to better inform the Committee on next steps to the NRP project. The Committee was thanked for their work in the development of the guidance document.

Next Steps

The Committee will await further direction from HRSA on the NRP project.

3. Public Comment Presentation: Modify Lung Donor Data Collection

A representative of the OPTN Lung Transplantation Committee (the Lung Committee) presented the Establish Comprehensive Multi-Organ Allocation Policy request for feedback.

Summary of discussion:

The Committee thanks the Lung Committee for their efforts on the Modify Lung Donor Data Collection proposal and the opportunity to comment. The Committee provided the following feedback:

The Committee Chair suggested a collected voice from the OPTN to advocate for a change in the Universal Donor Risk Assessment Interview (uDRAI). With this being a universal/uniform document that all members use, it would be important to update this as well. Currently, the uDRAI specifically only addresses smoking history. For most donor families, if asked, “Do you smoke?” but they vape, the answer would most likely be “no”. It is understandable why this information is needed and why the questions being proposed are more granular in nature. In helping to have a collective voice of having this updated in the system as this would not be a quick process. If this data collection proposal is moved forward, and this is not supported, members would be required to do addendums and additional documentation in order to accomplish the goal.

A member agreed with this and added that an update to the uDRAI would work well in tandem. There has been some updates to the uDRAI with some recent tissue guidance. With support from the OPTN, it would be great to have this happen at the same time.

There were no additional questions or comments.

Next Steps

The Committee’s feedback will be submitted for public comment for the Lung Committee’s consideration.

4. Public Comment Presentation: Establish Comprehensive Multi-Organ Allocation Policy

A representative of the OPTN Ad Hoc Multi-Organ Transplantation (MOT) Committee (the MOT Committee) presented the Establish Comprehensive Multi-Organ Allocation Policy request for feedback.

Summary of discussion:

The Committee thanks the MOT Committee for their efforts on the Establish Comprehensive Multi-Organ Policy request for feedback and the opportunity to comment. The Committee provided the following feedback:

The Committee Chair acknowledged the Committee’s historical feedback on allocation. As multi-organ allocation tends to be a challenge, this is an important topic and process to absorb.

The MOT Committee representative acknowledged the complexity of the topic and stated that members had multiple opportunities to review the proposal during regional meetings. OPTN Contractor staff added that after the request for feedback, the MOT committee plan to submit a policy proposal during the summer 2025 public comment cycle. The feedback received will help to inform the Committee in their development of the upcoming policy proposal.

The Committee Vice Chair commended the MOT Committee on the request for feedback on such a complex topic. The Committee Vice Chair asked the following:

- What is the role of these concepts for late turn downs for MOT recipients and the role for that in non-utilization and placement of sometimes difficult organs (i.e. pancreas offers that are intraoperative turn downs)

- The incremental benefits in terms of efficiency and equity that would come from this policy proposal would pale in comparison to all the allocation out of sequence (AOOS) that is happening. How would these concepts fit into AOOS?

The MOT Committee representative responded that these topics tie together. It is not thought the concepts in the request for feedback would not change the challenges of late turn downs. This should not increase it, but it will be the same way that members handle late turn downs now. Nothing changes how this would be handled with the prioritization tables that were presented. There would not be anything written into the policy or any expectations that it will change that situation. For AOOS, the majority of that are the higher KDPI kidneys, which is not relevant to MOT allocation. Due to this, it is not believed that the upcoming policy proposal would increase or decrease the AOOS piece.

OPTN Contractor staff added that the way this policy is designed, there will hopefully be increased capacity to monitor compliance with multi-organ allocation policy. Secondly, the system solution that is under development would hopefully proactively guide the user through this complex policy again, which is the hope to support compliance at the front end and increase compliance monitoring at the back end.

There were no additional questions or comments. The meeting was adjourned.

Next Steps

The Committee's feedback will be submitted for public comment for the MOT Committee's consideration.

Upcoming Meetings

- Thursday, April 24, 2025 (Teleconference)

Attendance

- **Committee Members**
 - Kim Koontz
 - Steve Potter
 - Anja DiCesaro
 - Anne Krueger
 - Annemarie Lucas
 - Bridget Dewees
 - Amanda Bailey
 - Elizabeth Shipman
 - Jillian Wojtowicz
 - Laura Huckestein
 - Megan Roberts
 - Nicole Toran
 - Norihisa Shigemura
- **SRTR Staff**
 - N/A
- **HRSA Staff**
 - N/A
- **UNOS Staff**
 - Joann White
 - Kelley Poff
 - Kerrie Masten
 - Niyati Upadhyay
 - Sarah Roache
 - Susan Tlusty
- **Guest**
 - Claire Morgan
 - Matthew Hartwig
 - Zoe Stewart