

Meeting Summary

OPTN Lung Transplantation Committee Meeting Summary August 31, 2023 Conference Call

Marie Budev, DO, Chair Matthew Hartwig, MD, Vice Chair

Introduction

The Lung Transplantation Committee (the Committee) met via Webex teleconference on 8/31/2023 to discuss the following agenda items:

- 1. Welcome and agenda
- 2. Ethical Analysis of Normothermic Regional Perfusion
- 3. Modify Organ Offer Acceptance Limit
- 4. Deceased Donor Support Therapy Data Collection
- 5. Continuous Distribution of Hearts
- 6. Public comment update
- 7. Next steps and closing comments

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

1. Welcome and agenda

Summary of discussion:

There was no further discussion by the Committee.

2. Ethical Analysis of Normothermic Regional Perfusion

The Committee received a presentation on the OPTN Ethics Committee's proposal, <u>Ethical Analysis of Normothermic Regional Perfusion</u>.

Summary of Discussion:

Decision #1: The Committee supports this proposal.

A member encouraged the OPTN Ethics Committee to examine the differences between abdominal and thoracic normothermic regional perfusion (NRP) and any potential negative effects on other organs, particularly the lungs.

3. Modify Organ Offer Acceptance Limit

The Committee reviewed the OPTN Organ Procurement Organization (OPO) Committee's proposal, Modify Organ Offer Acceptance Limit.

Summary of discussion:

Decision #2: The Committee generally supports this proposal if certain exceptions are incorporated into the final policy.

Members emphasized concurrent acceptance is not common in lung transplantation and it is important to retain this option for the rare circumstances in which it is needed. Members urge the OPTN OPO Committee to make an exception for donation after circulatory death (DCD) donors as they become more utilized. A member noted this concurrent acceptance practice is only a problem in liver transplantation and concurrent acceptance is used in lung transplantation when it is essential for more aggressive transplant program practices.

4. Deceased Donor Support Therapy Data Collection

The Committee received a presentation on the OPTN Operations and Safety Committee's proposal, <u>Deceased Donor Support Therapy Data Collection</u>.

Summary of discussion:

Decision #3: The Committee supports this proposal.

A member encouraged the OPTN Operations and Safety Committee to consider adding a data element for ventilator settings.

5. Continuous Distribution of Hearts

The Committee reviewed the OPTN Heart Transplantation Committee's proposal, <u>Modify Organ Offer Acceptance Limit</u>.

Summary of discussion:

Decision #4: The Committee supports the OPTN Heart Transplantation Committee as they move towards continuous distribution.

Members urged the OPTN Heart Transplantation Committee to consider access to transplant for congenital heart-lung candidates, specifically those with heart status three through five, as these patients are very ill and seem to wait a long time for transplant. The Chair noted it has been a challenge to transplant these candidates due to most of these heart offers being unsuitable for multi-organ candidates, and because the heart status generally drives allocation for these candidates (the heart pulls the lung). These candidates appear to be disadvantaged in the current system.

6. Public comment update

On August 24, 2023, staff conducted outreach to the following stakeholders to encourage public comment on the *Modify Lung Allocation by Blood Type* proposal. Outreach included:

- All member announcement
- Lung program medical and surgical directors
- Stakeholder organizations
 - American Society of Transplantation, American Society of Transplant Surgeons,
 Association of Organ Procurement Organizations, The Organization for Donation and
 Transplant Professionals (NATCO), International Society for Heart and Lung
 Transplantation, Society of Thoracic Surgeons
- Patient outreach
 - Transplant Recipients International Organization, Second Wind Lung Transplant
 Association, Lung Transplant Foundation, Cystic Fibrosis Foundation, COPD Foundation,
 Wescoe Foundation

Another reminder was sent to lung transplant programs on April 28, 2023. A final reminder will be sent on September 5, 2023. There are 16 comments to date including five from patients and donor families. Some general themes seen in public comment to date are:

- Overall support for policy change and rapid response
- Scaling up to five points may overcorrect and disadvantage other blood types while blood type
 O candidates are transplanted after implementation
- Five points in reference to other attributes may be out of proportion (i.e. medical urgency 95th percentile is 2.265 points)
- Blood type O candidates are being disadvantaged before the implementation of this policy change

Summary of discussion:

Decision #5: The Committee will review data to determine whether additional action is needed before implementation of *Modify Lung Allocation by Blood Type*.

Members voiced concern over blood type O candidates who need transplants before implementation. The Review Board Chair asked staff to review the timeline for implementation. The timeline is as follows:

- September 7th: Public comment closes at 11:59 pm ET
- September 11th: Public comment analysis sent to Committee
- September 14th: Lung Committee meets to:
 - o Review public comment feedback
 - Consider any post-public comment changes
 - o Vote to send proposal forward to the OPTN Board of Directors (BOD) for approval
- September 22nd: OPTN BOD votes on implementing proposal
- September 27th: IT implementation of blood type point changes (if BOD approves)

The Review Board Chair asked the Committee what score should be approved for exception requests if blood type O candidates are granted exceptions. Staff noted that OPTN guidance would need OPTN BOD or OPTN Executive Committee approval.

The Committee reviewed data that shows the number of waiting list removals for death or too sick is not greater than the previous allocation system since implementation of <u>Establish Continuous</u> <u>Distribution of Lungs</u>. A member noted quick changes, especially changes that are not based on solid data and do not include public comment, sets a dangerous precedent.

7. Next steps and closing comments

The Chair thanked members and presenters for joining the meeting.

Summary of discussion:

There was no further discussion by the Committee.

Upcoming Meetings

September 6, 2023, teleconference, 4:30 pm ET

Attendance

Committee Members

- o Marie Budev
- o Erika Lease
- o Brian Armstrong
- Brian Keller
- o David Erasmus
- o Errol Bush
- o Jackie Russe
- o Julia Klesney-Tait
- o Stephen Huddleson
- o Soma Jyothula
- Serina Priestly
- o Sid Kapnadak
- o Thomas Kaleekal
- o Tina Melicoff
- o Wayne Tsuang

HRSA Representatives

- o Jim Bowman
- o Marilyn Levi

SRTR Staff

- o David Schladt
- o Nicholas Wood
- Katherine Audette

UNOS Staff

- o Alex Carmack
- o Joann White
- o Katrina Gauntt
- o Kieran McMahon
- o Taylor Livelli
- o Eric Messick
- o Rober Hunter
- o Sara Rose Wells
- o Susan Tlusty
- o Samantha Weiss
- o Holly Sobczack
- o Rachel Hippchen

• Other Attendees

- Kurt Shuttterly
- o Rocky Daly
- o Sanjay Kulkarni
- Kimberly Koontz