OPTN Ad Hoc Multi-Organ Transplantation Committee
Lung Multi-Organ Workgroup
Meeting Summary
September 24, 2024
Conference Call

Marie Budev, DO, MPH, Chair
Lisa Stocks, RN, MSN, FNP, Chair

Introduction

The OPTN Lung Multi-Organ Workgroup (the Workgroup) met via WebEx teleconference on 09/24/2024 to discuss the following agenda items:

1. Review SRTR analysis
2. Review OPTN analysis
3. Discuss potential lung CAS thresholds

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

1. Review SRTR analysis

SRTR contractor staff presented the SRTR analysis.

Summary of Presentation:

The aim is to support decisions on composite allocation score (CAS) threshold for required shares to multiorgan lung candidates. SRTR contractor staff presented an overview of the methodology:

Models:

- Time-to-event (Cox proportional hazards) models
- Outcomes
    - Waiting list: Death (including after removal for reasons other than transplant)
    - Posttransplant: All-cause graft failure
- Variables
    - CAS
    - Multiorgan indicators
    - Covariates identified as relevant in SRTR program-specific reports (PSRs)
- Report – Nonlinear relationship of CAS to death or graft failure

SRTR contractor staff demonstrated how this analysis was incorporated into an interactive online tool that allows the user to set a CAS threshold and a constant for the placement efficiency score. The tool shows the proportion of observations in the model above and below a given threshold, broken down by waitlist mortality score, posttransplant mortality score, and organs needed. SRTR contractor staff showed an example using a CAS threshold of 35 and a placement efficiency score of 7. In the lung CAS, candidates within 1,000 nm of the donor hospital receive at least 7 points for placement efficiency.

> **The OPTN Lung Multi-Organ Workgroup did not make any decisions.**

The Chair requested information at different CAS thresholds (28 and 31) to get a sense of how small incremental changes affect the distribution.

SRTR Contractor staff showed a CAS threshold of 28 (assuming a placement efficiency score of 7): About 78% of observations were above a CAS of 28. Most observations on both sides of this threshold had a low waitlist mortality score (0-2). The proportion of observations below and above the threshold were about the same for lung-alone and heart-lung candidates. The proportion of lung-kidney observations above the threshold was about 1.1 %, which was lower than the observed percentage with a CAS threshold of 35, though SRTR contractor staff said that likely represented a substantial number of candidates.

SRTR Contractor staff showed a CAS threshold of 31 (assuming a placement efficiency score of 7): The proportion of observations for multi-organ candidates above and below the threshold did not change significantly, though there were fewer multi-organ candidates overall above the threshold. The posttransplant score distribution remained about the same. The waitlist mortality scores showed the most changes as the higher waitlist mortality scores appear more frequently at this threshold, and the distribution of observations is closer to 50/50, with 43% below a CAS of 31.

Next steps

None were discussed.

2. Review OPTN analysis

OPTN contractor staff presented on the OPTN analysis.

Presentation summary:

The Ad-Hoc Multi-Organ Transplantation (MOT) Committee is in the process of developing their allocation algorithms – a ranked priority list for OPOs to follow when they are allocating multiple organs from the same donor.

The main goal of this analysis was to reevaluate whether a CAS threshold of 25 is appropriate for required lung multi-organ sharing.

Summary of discussion:

> **The OPTN Lung Multi-Organ Workgroup did not make any decisions.**

The Chair asked about the context of match run sizes as a very large match run of over 600 was mentioned. UNOS staff clarified that that 50% of match runs are for blood type O donors, which tend to be larger. Other blood types have fewer compatible candidates and smaller match runs. Organ procurement organizations (OPOs) are not necessarily offering organs that far down each match run; the data shown was to illustrate variability.

Blood type AB candidates can appear on match runs for donors of all blood types. The plot showing lung CAS by sequence number for AB candidates shows two groupings, where the group with the higher sequence numbers likely represents AB candidates appearing on O donor match runs, whereas the group with the lower sequence numbers likely represents AB candidates appearing on match runs for donors of other blood types.

The data showed that 46% of heart-lung candidates had an approved heart exception. One member asked if the analysis looked at heart and lung transplants separately. UNOS staff confirmed that the match runs for heart and lung are independent. There was a discussion about whether the Lung Review Board is stricter than the Heart Regional Review Boards in granting exceptions, with mixed opinions. Another member asked about whether exceptions were granted for Status 3 or 4 candidates. UNOS staff answered that they did not have that specific data at this time.

Another member showed interest in the change in CAS scores relative to time to transplant for blood type O candidates, but this specific analysis was not performed.

Next steps

None were discussed.

3. Discuss potential lung CAS thresholds

OPTN contractor staff presented on the different lung CAS thresholds.

Presentation summary:

Discussion:

- What CAS threshold would you recommend as the "highly urgent/highly prioritized" CAS threshold?
- What CAS threshold would you recommend as the "less urgent/less prioritized" threshold?
- Should the thresholds vary by blood type or by other components of the CAS?

Summary of discussion:

> **The OPTN Lung Multi-Organ Workgroup did not make any decisions.**

Members discussed the complexity of heart-lung transplants and that changing the lung CAS threshold is not likely to improve access to heart-lung transplant. The data showed that 29 heart-lung recipients were offered the organs off the heart match, and 7 heart-lung recipients were offered the organs off the lung match. Most of the recipients transplanted from the heart match had adult heart status of 1 or 2 (27 out of 29) whereas more of the recipients transplanted from the lung match had adult heart status 4 (5 of 7 recipients). However, the MOT proposal includes implementing directions in the system for OPOs on the order in which to make organs across the various organ match runs, including when to move to the lung match from the heart match for required multi-organ lung offers. The group discussed that access to heart-lung transplant may need to be addressed by the OPTN Heart Transplantation Committee.

Members discussed setting an appropriate CAS threshold for lung candidates in multi-organ scenarios. The group considered a threshold around 30 but expressed concern about how this threshold would affect different blood types, particularly type O candidates.

Blood type O candidates tend to have higher CAS scores due to longer wait times. The group considered separate thresholds for blood type O versus other blood types (A, B, AB).

Members expressed concerns about the quality and interpretation of the data, given anecdotal discussions about variability in how OPOs implement the multi-organ policies. The group wants to ensure that the data accurately reflects policy intentions rather than varied interpretations. UNOS staff explained that much of the analysis focused on where candidates appeared on the match run rather

than how OPOs were making offers to remove that element of variability and provide consistent data for comparison.

A HRSA representative raised concerns about the small sample sizes and the need for clinical input alongside statistical analysis. They suggested implementing an allocation scheme based in part on clinical judgement and monitoring outcomes, recognizing the limitations of predictive modeling.

<u>Next steps</u>

The Workgroup plans to review the data further hold another meeting to discuss thresholds. They are considering requesting more granular data and analysis to inform their decision.

Upcoming Meeting

- o To be determined.

Attendance

- **Workgroup Members**
  - Marie Budev
  - PJ Geraghty
  - Jasleen Kukreja
  - JD Menteer
  - Jackie Russe
  - Chris Sonnenday
  - Matt Hartwig
  - Shelley Hall
  - Shunji Nagai
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Jon Miller
- **UNOS Staff**
  - Viktoria Filatova
  - Katrina Gauntt
  - Chelsea Hawkins
  - Krissy Laurie
  - Kaitlin Swanner
  - Sarah Roache
  - Houlder Hudgins
  - Laura Schmitt
  - Sara Langham
- **Others**
  - Gundeep Dhillon