

Meeting Summary

OPTN Lung Transplantation Committee Meeting Summary September 27, 2024 Conference Call

Matthew Hartwig, MD, Chair Dennis Lyu, MD, Vice Chair

Introduction

The Lung Transplantation Committee (the Committee) met via Webex teleconference on 9/27/2024 to discuss the following agenda items:

- 1. Background: Candidate Biology in Continuous Distribution
- 2. Public comment analysis: Promote Efficiency of Lung Donor Testing
- 3. Workgroup update: Multi-Organ Transplantation
- 4. Project update: Modify Lung Donor Data Collection
- 5. Implementation update: Six-Minute Walk for Lung Allocation
- 6. Update: Lung Review Board

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

1. Background: Candidate Biology in Lung Continuous Distribution

In recent meetings, the Committee has reviewed results from the Scientific Registry of Transplant Recipients (SRTR) data request. The Committee is evaluating whether changes to how candidate biology factors into Lung Continuous Distribution are needed.

Presentation Summary:

SRTR Data Request

The Committee received an overview of the SRTR data request results and follow-up analyses (**Appendix A**).

Changing Allocation Policy

Key steps to changing allocation policy were reviewed (**Appendix B**). OPTN and SRTR staff discussed a potential data request, possible approaches to rating scales and explained options for testing rating scales, including match run analysis, simulation modeling, and policy optimization. After identifying rating scales, the Committee can request match run analysis and results could be available in the short term. Simulation modeling could be requested; this would require approximately 6-8 months' lead time. Policy optimization could be performed by MIT and would take approximately 7-9 months. In development of CD, other organs are also interested in resources for modeling. The OPTN Executive Committee will review the matter and determine how projects will be sequenced.

Summary of discussion:

The Committee decided to proceed with a project to change how biological factors are incorporated into lung allocation.

The Committee requested additional data to inform the development of new rating scales for biological factors.

The Committee decided to proceed with a project to change how biological factors are incorporated into lung allocation. Members agreed that addressing the disadvantages faced by certain biological groups is important for improving access. It was noted that, while it is impossible to achieve absolute equity in transplant, access between candidates with different biological factors, there is room for improvement. However, to achieve more equitable access for certain candidates with biological disadvantages, transplant rates would decrease for other candidate groups.

There is a need to determine how much the system can be improved, particularly regarding blood type O donors going to non-O recipients. The Committee requested additional data to better understand this and inform the development of new rating scales. A high-level explanation of the request is available in **Appendix C**. Members listed several donor characteristics of interest for this data request.

There was interest in proceeding with both match run analysis and simulation modeling. The SRTR opinion was that match run analysis would be sufficient if changes to the rating scales were to be small. Members expressed concerns about the potential impact of changing allocation policy on waitlist mortality, which significantly improved under CD.

Next steps

The Committee will receive a presentation from the National Institutes of Health (NIH) funded team that developed an alternate rating scale combining blood type and height and consider whether other approaches should be evaluated.

2. Public comment analysis: Promote Efficiency of Lung Donor Testing

The *Promote Efficiency of Lung Donor Testing* proposal was available for community feedback during the Summer 2024 Public Comment (PC) cycle.

Summary of discussion:

No final decisions were made as far as post-PC changes to the proposal.

The Committee reviewed the PC analysis for the *Promote Efficiency of Lung Donor Testing* proposal. No final decisions were made as far as post-PC changes to the proposal. The Committee made several recommendations for the Promote Efficiency of Lung Donor Testing Workgroup (Workgroup) to consider.

Regarding echocardiogram (echo) and right heart catheterization (RHC), there was a suggestion for stronger language than "if performed" and documentation of why an Echo or RHC could not be done. For DCD donors, members suggested that lacking an echo/RHC should not prevent offers from being sent by the Organ Procurement Organization (OPO).

Arterial Blood Gases (ABGs)

There was discussion of different ABG requirements for DCD and DBD donors and extended timelines for ABGs, to address differences between DCD and DBD donation pathways. For DBD donors, members suggested within 4 hours prior to offer, 8 hours between the time of the initial offer and organ offer acceptance, and at least every 8 hours between organ acceptance and organ recovery. For DCD donors, members suggested within 4 prior to offer, at least every 12 hours between the time of the initial offer until organ recovery. Community feedback noted, and Committee members from OPOs agreed, that

extended ABG timelines may account for challenges in testing DCD donors. For both donor types, the Committee recommended OPO document when/why ABGs are not able to be completed.

Proposed requirements for ABG testing include positive end expiratory pressure (PEEP) of 5-8 cmH2O; Committee members were split on whether to extend PEEP range to 5-10 cmH2O. Members commented that an expanded range may account for donors with different characteristics. However, some members felt retaining the proposed range would ensure standardization. Additionally, a member with pediatric lung expertise commented that a PEEP of 10 would not be appropriate for pediatric donors.

There was support for using the National Heart, Lung, and Blood Institute (NHLBI) formula for Ideal Body Weight (IBW). This formula is not validated in pediatric patients. It may be appropriate to only use the formula for donors 18 years or older, and 5 feet and taller.

Regarding feedback on recruitment maneuvers, members commented that there are too many recruitment maneuvers to list. There may need to be clarification of the intent behind this proposed requirement.

Chest computed tomography (CT) scan

The Committee suggested stronger language than "if performed" and documentation of when/why a chest CT scan is not able to be completed. It should be clear that a CT scan is expected unless there are significant barriers or efficiency concerns.

Next steps

The Workgroup will review the PC analysis and the Committee's feedback on this proposal.

3. Workgroup update: Multi-Organ Transplantation

The Multi-Organ Transplantation (MOT) Committee is developing a policy proposal to promote equitable access to transplants among multi- and single-organ candidates and promote consistent and efficient allocation practices. The OPTN Lung MOT Workgroup is evaluating current lung MOT policies and considering changes to be incorporated into the MOT Committee's proposal.

Summary of discussion:

No decisions were made.

There are community concerns that offering through all lung multi-organ candidates with a CAS of 25 or greater before offering to liver-alone candidates creates allocation challenges. The MOT Committee recommends two CAS thresholds to fit into algorithm(s): a highly urgent/highly prioritized CAS threshold and a slightly less urgent CAS threshold.

The Committee reviewed OPTN and SRTR analyses related to this work, which was presented to the Lung MOT Workgroup on <u>September 24, 2024.</u> Members provided feedback on an interactive tool created by SRTR staff that would assist in the interpretation of key data informing decision-making about lung CAS thresholds for MOT allocation.

Next steps:

The Lung MOT Workgroup aims to recommend CAS thresholds to the MOT Committee before the next MOT Committee in-person meeting on October 30, 2024.

4. Project update: Modify Lung Donor Data Collection

The Promote Efficiency of Lung Donor Testing Workgroup (Workgroup) has been developing a proposal to improve the efficiency of lung allocation for OPOs and lung transplant programs by making it easier for lung transplant programs to say "yes" to organ offers. This project involves adding data collection for Predicted Total Lung Capacity (pTLC), peak inspiratory pressure (PIP), marijuana smoking history, vaping history and updating data collection for cigarette smoking history and diagnostic test status.

Presentation summary:

There was a review of data elements in the project. Mockups of data fields in the OPTN Donor Data and Matching System were displayed.

On July 11, 2024, the Promote Efficiency of Lung Allocation Workgroup sought feedback on TLC from the Lung Committee. The Committee advised:

- Preference for pTLC, as it is more commonly available than actual TLC (aTLC)
- OPTN Donor Data and Matching System function: Calculate pTLC using already collected data
- OPTN Waiting List Function: Allow user to enter absolute minimum and maximum range
- Donors outside of this range would be screened off

On August 13, 2024, when reviewing additional questions about the ERS formula, the Workgroup suggested consulting with experts at Pulmonary Function Testing (PFT) laboratories. PFT experts recommended to use the GLI formula.

Limitations and considerations of the pTLC GLI formula were reviewed. Presenters noted that the formula was developed on an all White, European cohort. Limitations and guidelines for interpretation are described in an article by European Respiratory Society (ERS) and American Thoracic Society (ATS): ERS/ATS technical standard on interpretive strategies for routine lung function tests¹. It was noted that this is a race-neutral formula.

Summary of discussion:

The Committee recommended proceeding with the pTLC GLI formula, despite limitations. Members suggested displaying a disclaimer in the OPTN system to bring awareness to the limitations of the formula.

Overall, there was support for the Workgroup's recommendations to date and no concerns were noted.

The Committee recommended proceeding with the pTLC GLI formula, despite limitations. Though using the formula is not optimal, this is the best option available. Given the great need to increase efficiency in lung allocation and the formula's utility in size-matching, members felt it would be justified to use this formula until a calculation is validated against a more diverse cohort. Members suggested displaying a disclaimer in the OPTN system to bring awareness to the limitations of the formula.

Next steps:

The Workgroup will finalize and consider recommending the project to the Committee during their November meeting.

¹ European Respiratory Journal 2021; 60(1): 2101499; DOI: https://doi.org/10.1183/13993003.01499-2021.

5. Implementation update: Six-Minute Walk for Lung Allocation

Standardize Six Minute Wal for Lung Allocation was implemented on September 3, 2024. This policy requires lung transplant programs to do the following:

- Ensure that oxygen titration tests are completed ahead of the initial six-minute walk test conducted for lung candidates at least 12 years old, and for the six-minute walk test conducted just before candidates turn 12 years old.
- For lung candidates registered prior to September 3, 2024, who are at least 11 years 6 months old on September 3, 2024, transplant programs must perform an oxygen titration test prior to conducting the six-minute walk test for reporting a six-minute walk distance by March 3, 2025.

The Committee has received inquiries on effective practices for implementation.

Summary of discussion:

The Committee will reassemble the Six Minute Walk workgroup to develop implementation resources.

The Committee discussed the need for implementation resources and community education including a live forum and best practices video. They mentioned challenges such as needing more time to adapt to new workflow processes and some members voiced barriers with billing in that insurance will not allow for both tests to be completed on the same day.

The Committee concurred that documentation and distribution of effective practices for implementation would aid the community. Members agreed that the Six Minute Walk workgroup should be reassembled to develop these resources.

Next steps:

The Six Minute Walk Workgroup will meet and discuss the development of necessary resources.

6. Update: Lung Review Board

The Committee heard about recent efforts of the Lung Review Board.

Summary of discussion:

No decisions were made.

The Committee was asked to submit examples of standard exceptions for the Lung Review Board to discuss as they develop sample templates for lung transplant programs to use. The Committee looked at data where exceptions were "approved due to time limit". Either seven or eight out of nine total voters responded to each case that was approved due to time limit. The Committee observed that the most prevalence of cases approved due to time limit in quarter 4 of 2023 and quarter 2 of 2024.

Next steps:

The Committee will receive another Lung Review Board update during a future meeting.

Upcoming Meetings

• October 10, 2024, 5 PM ET, teleconference

Attendance

Committee Members

- Matthew Hartwig
- o Dennis Lyu
- Marie Budev
- Joseph Tusa
- o Jaclyn Russe
- o Thomas Kaleekal
- o Jordan Hoffman
- o David Erasmus
- o Ed Cantu
- o Brain Armstrong
- o Gary Swartz
- o Heather Strah
- o Tina Melicoff
- o Katja Fort Rhoden
- o Serina Priestley
- Wayne Tsuang

HRSA Representatives

- o James Bowman
- o Marilyn Levi

SRTR Staff

- o David Schladt
- o Katie Audette
- o Maryam Valapour
- Nick Wood
- o Grace Lyden

UNOS Staff

- o Kelley Poff
- o Kaitlin Swanner
- o Chelsea Hawkins
- o Houlder Hudgins
- o Samantha Weiss
- o Susan Tlusty
- o Sara Rose Wells
- o Carson Yost
- o James Alcorn
- Sarah Roache

Other attendees

- o Lisa Stocks
- o Zoe Stewart Lewis

Appendices

Appendix A: SRTR Follow-up Analysis

Follow-up analysis: Transplant rate by height and diagnosis

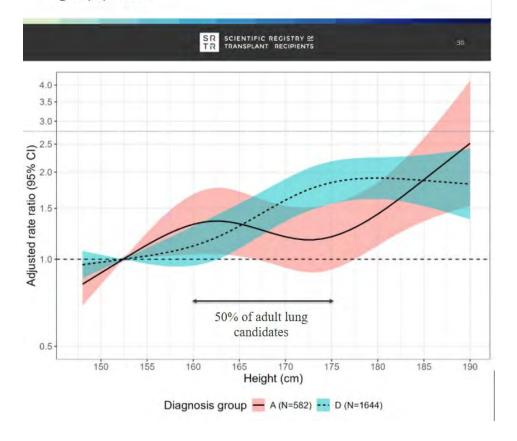
Allowed height effect to vary by diagnosis group

· Still adjusted for ABO, WLAUC

Focus: Diagnosis groups A (obstructive) and D (restrictive)

What we found:

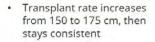
 Borderline significant interactions between height and diagnosis group (p=0.057)



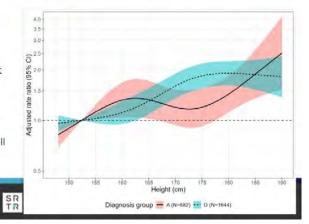
Comparing 75th to 25th percentile of height

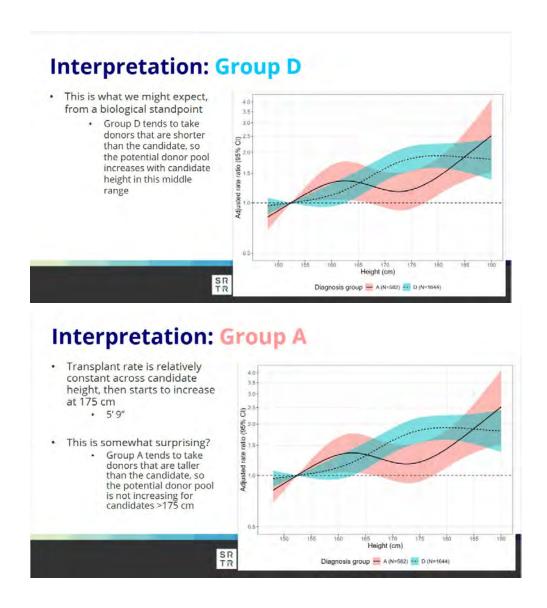
Diagnosis	Adjusted rate ratio (95% CI) comparing 5'9" to 5'3" adult lung candidates
Group D	1.66 (1.41, 1.97)
Group A	0.91 (0.66, 1.25)
All groups	1.47 (1.28, 1.70)

Interpretation: Group D

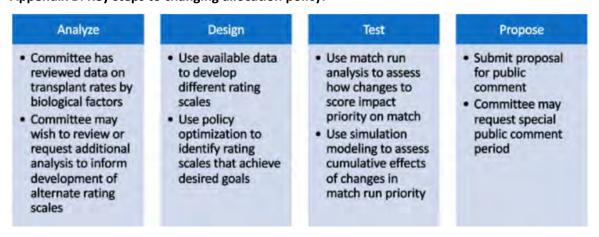


- <u>Similar to</u> overall height effect in the report
 - This makes sense because Group D is the largest diagnosis group, contributing the most information to the overall effect





Appendix B: Key steps to changing allocation policy.



Appendix C: Description of data request.

Characteristics of ABO Compatible Transplants

- Recipient Characteristics
 - Summary of CAS attributes for patients who received ABO compatible organs vs. ABO identical organs
- · Donor Characteristics:
 - Summarize characteristics of donors to determine if these are more medically complex donors
 - Examine match run data were ABO identical candidates offered organs and declined before ABO compatible candidates accepted?