

OPTN Lung Transplantation Committee

Meeting Summary

January 11, 2024

Conference Call

Marie Budev, DO, MPH, Chair

Matthew Hartwig, MD, Vice Chair

Introduction

The Lung Transplantation Committee (Committee) met via Webex teleconference on 01/11/2024 to discuss the following agenda items:

1. Public Comment proposal: *Expedited Placement Variance*
2. Candidate Biology in Continuous Distribution (CD)
3. Open Forum

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

1. Public Comment proposal: *Expedited Placement Variance*

The *Expedited Placement Variance* [proposal](#) is sponsored by the OPTN Executive Committee. The proposal suggests a new variance to govern pilot projects related to expedited organ placement and updates to the OPTN's governance structure regarding variances.

Summary of discussion:

The Committee supports the development of a new variance to govern pilot studies related to expedited placement protocols. However, members urged the OPTN Executive Committee to provide more detailed information about the approval process, monitoring, and evaluation plans for these pilot studies.

The Committee supports the development of a new variance to govern pilot studies related to expedited placement protocols and commends the Executive Committee's efforts to provide equal access to participate in these protocols. The Committee asked the Executive Committee to consider the importance of maintaining transparency throughout the process of reviewing and implementing proposed protocols for expedited placement of hard-to-place organs. Key terms associated with a given protocol should also be clearly defined to ensure consistency in execution. The Committee raised concerns regarding potential interactions between approved protocols and members noted that approving multiple variances involving the same organs in the same locale could make it difficult to discern the impact of each protocol independently. It was discussed that each approved variance should assume neutral impact on the allocation of other organs. Members urged the OPTN Executive Committee to provide more detailed information about the approval process, monitoring, and evaluation plans for these pilot studies, including specific key metrics to measure success and potential

downstream effects. Members also suggested that proposed pilot studies be reviewed and monitored by a patient safety board.

Although [non-use rates](#) for lungs are relatively low compared to other abdominal organs, such as [kidneys](#), some members noted that this proposal provides a pathway to increase lung transplant volume beyond that of recent advancements in innovation, such as ex vivo lung perfusion (EVLP). A committee member from a lung transplant program commented that some donor hospitals have more resources or different protocols that may promote the use of donor organs. There may be an opportunity to leverage data from the proposed pilot studies to identify key criteria that defines “hard-to-place lungs”. Establishing this definition was identified as a potential first step towards proposing expedited placement variance protocols for lungs.

Next steps:

The Committee will submit their feedback on the *Expedited Placement Variance* proposal during the special public comment period. The Committee will discuss potential expedited placement protocols for lungs in future meetings.

2. Candidate Biology in Continuous Distribution (CD)

On December 14, 2023, the Committee confirmed their interest in working on changes to the sensitization, or Calculated Panel Reactive Antigen (CPRA), and height rating scales used to calculate lung composite allocation scores (CAS). On December 19, 2023, the Scientific Registry of Transplant Recipients (SRTR) and Massachusetts Institute of Technology (MIT) recommended: exploring approaches for defining biological incompatibility rather than modeling changes to the rating scales; allowing more monitoring data to accumulate to assess performance of the lung allocation system; considering analyses on biological characteristics that are not dependent on allocation policies to develop research questions before consulting with SRTR and MIT.

To better understand the impact of CD on biologically disadvantaged groups, the Committee reviewed data from SRTR showing time trends in lung transplant and waitlist mortality rates, overall and stratified by height.

Data Summary:

The following describes trends from January 1, 2016 to December 2, 2023, and excludes pediatric candidates.

Deceased donor transplant rate:

- Continues to increase slowly overall
- Pre-CD: Highest for tallest candidates, lowest for shortest candidates (<150cm)
- Post-CD: Sharp increase for shortest candidates (<150cm) after implementation of CD, while maintaining slow incline in other height categories

Waitlist mortality rate:

- Significant decrease overall after implementation of CD
- Lacks clear trends when stratified by height

Summary of discussion:

No decisions were made.

Transplant rates by height indicate that the height rating scale implemented with CD gives meaningful priority to the shortest candidates but does not for moderately short candidates. An SRTR representative emphasized that although waitlist mortality rates by height were difficult to interpret, there were no notable changes post-CD implementation. It was discussed that sample sizes are too small for pediatric candidates to discern any trends in pediatric waitlist mortality. Members noted the importance of informing the Lung Review Board of discussions surrounding the biological disadvantages rating scales.

Next steps:

The Committee will review additional monitoring data stratified by height and CPRA in future meetings.

3. Open Forum

There were no open forum speakers.

Upcoming Meeting

- February 8, 2024, teleconference, 5PM ET

Attendance

- **Committee Members**
 - Marie Budev
 - Ernestina Melicoff
 - Errol Bush
 - Wayne Tsuang
 - Brian Keller
 - Ed Cantu
 - Erika D. Lease
 - David Erasmus
 - Soma Jyothula
 - Julia Klesney-Tait
 - Pablo Sanchez
- **HRSA Representatives**
 - James Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Nick Wood
 - David Schladt
 - Maryam Valapour
- **UNOS Staff**
 - Kelley Poff
 - Kaitlin Swanner
 - Leah Nunez
 - Sara Rose Wells
 - Susan Tlusty
 - Houlder Hudgins
 - Samantha Weiss
 - Chelsea Weibel
 - Holly Sobczak
- **Other Attendees**
 - Paul Gunsalus