OPTN Lung Transplantation Committee
Meeting Summary
December 15, 2022
Conference Call

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

Introduction

The Lung Transplantation Committee (the Committee) met via Citrix GoTo teleconference on 12/15/2022 to discuss the following agenda items:

1. Welcome and agenda
2. Board of Directors Meeting Update
3. Continuous Distribution Policy Clarification
   - **VOTE:** Do you support sending this clarification to the Executive Committee in January 2023?
4. Continuous Distribution Implementation Update
5. Additional Composite Allocation Score Analysis
6. 6-month monitoring report: Updates to the Lung Allocation Score
7. Next Steps and Closing Comments

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

1. Welcome and agenda

The Chair welcomed Committee members.

Summary of discussion:

There was no further discussion by the Committee.

2. Board of Directors Meeting Update

Staff updated the Committee that the Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution, Update Multi-Organ Allocation for Continuous Distribution of Lungs, and the Update Data Collection for Lung Mortality Models proposals were all approved by the OPTN Board of Directors on December 5, 2022 without amendment.

The OPTN Executive Committee also approved moving the Establish Continuous Distribution of Lungs implementation to March 2, 2023.

Summary of discussion:

There was no further discussion by the Committee.

3. Continuous Distribution Policy Clarification

   - **VOTE:** Do you support sending this clarification to the Executive Committee in January 2023?

This clarification addresses an issue with the height incompatibility table in OPTN policy. This policy clarification will replace Table 21-9 with correct values for proportion of incompatible donors based on lung height.[1]

This policy clarification also removes post-transplant survival probability for t = 1826 days. This is not needed because table covers day 0 to 1825, which is 1826 days.[2]

Summary of discussion:

Twelve members of the Committee voted to send this policy clarification to the OPTN Executive Committee (0-abstain, 0-no).

4. **Continuous Distribution Implementation Update**

Staff gave an overview of the timeline for implementation of continuous distribution as follows:

- December 16, 2022: Transplant coordinator webinar
- January 19, 2023: Patient webinar
- January 26, 2023: Updated calculated reactive panel antibody (cPRA) calculation implemented
- February 2, 2023: Composite Allocation Score calculator released
- Early February 2023: Another round of workshops/webinars
- February 9-23, 2023: Interim exception request window
- March 2, 2023: Implementation

Individual outreach was conducted for 100% of lung transplant programs. About 70% of lung transplant programs accessed their composite allocation score (CAS) report and 68% accessed an educational module, while 52% of lung transplant programs have attended a town hall.

Staff gave an overview of educational offerings that are currently available here:

- Available courses:
  - Basic Principles of Lung Continuous Distribution
  - Unacceptable Antigens & CPRA in Lung Continuous Distribution
  - Scoring and Exceptions under Lung Continuous Distribution
  - Preparing for Implementation of Lung Continuous Distribution
  - Using the Lung CAS Report
  - UNet for Lung Continuous Distribution
- Forthcoming offerings:
  - Pediatric Lung Allocation
  - Lung Review Board Orientation under Lung Continuous Distribution
  - Lung Continuous Distribution for OPOs

Summary of discussion:

The Chair asked if the Committee could receive a demonstration on the use of the CAS calculator before its release. Members agreed. Staff responded she would check internally to see if that is possible. The Chair said it is important the Committee is prepared for questions from the community.

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[1] "Establish Continuous Distribution of Lungs," OPTN, Mini-Brief, accessed January 10, 2023, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-continuous-distribution-of-lungs/
[2] Ibid.

5. Additional Composite Allocation Score Analysis

Staff gave an overview of the data request the Committee will make to further analyze the CAS. She suggested this will include:

1. Additional comparison of lung allocation score (LAS) and CAS

    - Scatter plot by age

    - Bar charts by diagnosis group and age groups

2. Impact of one-year waitlist urgency score (WLAUC) rating scale – scatter charts of LAS vs. CAS but calculate CAS using:

    - Linear WLAUC rating scale

    - Shallow slope WLAUC rating scale

3. Emphasis on analysis of ranking of sick patients under CAS – scatterplot of WLAUC vs. CAS by:

    - Diagnosis group (split out chronic obstructive pulmonary disease (COPD) and other A group diagnoses)

    - Estimated post-transplant survival

    - Pediatric status

    - Biological disadvantage (CPRA, blood type (ABO), and height)

    - Age

Summary of discussion:

Committee members thanked staff for their time and willingness to continue this analysis. SRTR staff stated she has concern over the WLAUC and post-transplant survival. She believes this analysis will help better explain this.

6. 6-month monitoring report: Updates to the Lung Allocation Score (LAS)

Staff provided an analysis of LAS by diagnosis groups before and after the LAS Modification in October 2021. The policy updated the variables, coefficients, and probabilities used in the LAS calculation. The new cohort was made up of lung candidates and recipients from March 1, 2015, through March 31, 2018. The primary goals of this policy change were to maximize post-transplant survival and waiting list outcomes for lung transplant recipients. The monitoring report examined October 1, 2021, to March 31, 2022, post-implementation.

Data Summary:

OPTN Waiting List:

The number of registrations added to the OPTN Waiting List increased slightly post-implementation. The distribution of age at registration decreased for all diagnosis groups slightly post-implementation. Match LAS at listing for diagnosis groups A, C, and D stayed consisted post-implementation. Diagnosis Group B Match LAS dropped post-implementation.

Outcomes:

Deaths per 100 patient years while waiting increased in diagnosis groups A, C, and D and decreased in diagnosis group B. Deaths per 100 patient years increased for all LAS groupings except for the group

with LAS from 20 to less than 30, and the group with LAS of 70 or greater. The increases and decreases are marginal and may not be statistically significant for this subgroup analysis.

Transplants per 100 active patient years decreased in every diagnosis group post-implementation. Transplants per 100 active patient years increased for LAS groups less than 20, 40 to less than 50, 50 to less than 60, and 60 to less than 70, and decreased in every other LAS grouping except for LAS group 20 to less than 30 where they remained at 0.

Transplants:

The number of transplants decreased in the post-policy era. The distribution of age of transplant recipients in diagnosis groups A, C, and D all had similar distributions post-implementation as they did pre-implementation. Diagnosis group B distribution of age increased post-implementation.

The mean LAS by era and diagnosis group A, B, and C all had slight drops post-implementation. Diagnosis group D had a slight increase post-implementation. The percent of exceptions at transplant increased in all diagnosis groups except for diagnosis group C where there were 0 percent of exceptions at transplant.

The mean difference between match and calculated LAS at transplant for recipients granted an exception decreased in diagnosis groups A, B, and C post-implementation, with only one recipient in diagnosis group A. There was an increase for diagnosis group D.

The distribution of calculated vs. match LAS at transplant is similarly distributed pre- and post-implementation for diagnosis group A and D. The scores at transplant are lower for diagnosis group B. Calculated and match LAS of diagnosis group C are lined up more closely post-implementation.

Summary of discussion:

SRTR staff noted the number examined for LAS group 60 to less than 70 must be very small. Staff explained that is the reason for the wide confidence intervals. The Past Chair noted the mean LAS may have decreased in diagnosis group C due to medication used to treat cystic fibrosis (CF).

SRTR staff noted the policy change dropped several variables for diagnosis group B and this has caused scores to decrease. The Past Chair agreed. Members agreed future monitoring reports may make it clearer if this decrease is statistically significant.

HRSA staff asked the difference between the calculated and match LAS at transplant. Staff explained the calculated LAS is the LAS equation and the match LAS considers any exceptions.

7.   Next Steps and Closing Comments

The Chair thanked members for their participation this past year.

Summary of discussion:

There was no further discussion by the Committee.

Upcoming Meetings

- January 19, 2023, 5PM EST, teleconference

Attendance

- **Committee Members**
  - Marie Budev
  - Erika Lease
  - Brian Armstrong
  - Dennis Lyu
  - Edward Cantu
  - Errol Bush
  - John Reynolds
  - Julia Klesney-Tait
  - Matthew Hartwig
  - Nirmal Sharma
  - Pablo Sanchez
  - Soma Jyothula
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
- **SRTR Staff**
  - Katherine Audette
  - Maryam Valapour
- **UNOS Staff**
  - Kaitlin Swanner
  - Taylor Livelli
  - Holly Sobczack
  - Krissy Laurie
  - Jesse Howell
  - Tatenda Mupfudze
  - Samantha Weiss
  - Sara Rose Wells
  - Susan Tlusty