

## **OPTN Lung Transplantation Committee**

### **Meeting Summary**

**March 21, 2024**

**Houston, TX**

**Marie Budev, DO, MPH, Chair**

**Matthew Hartwig, MD, Vice Chair**

### **Introduction**

The Lung Transplantation Committee met in Houston, TX on 03/21/2024 to discuss the following agenda items:

1. Biological disadvantages
2. Offer Filters update
3. Public comment analysis discussion: *Promote Efficiency in Lung Allocation*
4. Promote Efficiency of Lung Allocation Workgroup update
5. Expeditious task force update
6. Lung Review Board update
7. Public comment analysis discussion: *Standardize Six Minute Walk for Lung Allocation*

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

#### **1. Biological disadvantages**

The Committee continued their discussion on examining how transplant access varies by height and sensitization, or Calculated Panel Reactive Antibody (CPRA). The Scientific Registry of Transplant Recipients (SRTR) presented potential approaches for an adjusted analysis to explore equity in lung allocation based on height, CPRA, and blood type.

#### Data summary:

Preliminary adjusted analyses examining transplant access by candidate height were presented. The analyses controlled for medical urgency. There was evidence of disparity in transplant access by height; although medical urgency differs by candidate height, the disparity in access is not fully explained by these differences in medical urgency between groups. Preliminary results indicate that when medical urgency is the same, taller adult lung candidates have faster transplant rates than shorter adult lung candidates.

#### Summary of discussion:

The Committee agreed to proceed with a formal data request to SRTR for an adjusted analysis examining equity in lung allocation by height, CPRA, blood type. The Committee supported examining potential interactions between height & blood type in relation to transplant access.

While challenging due to data limitations, the Committee supported examining CPRA through sensitivity analysis. Some members expressed concern about the ability to interpret analyses using current CPRA data due to missing data and small samples sizes in the highly sensitized groups. As discussed in previous meetings, CPRA data is missing at non-random because of differences in transplant program behavior. It was explained that the primary concern with current CPRA data is that it is difficult to

distinguish between candidates that are truly not sensitized and those that are slightly to moderately sensitized, but no data were entered. Strategies were discussed to distinguish "true" zeros from unreported/missing values using declined organ data. There was agreement that CPRA data for highly sensitized candidates would be accurate, and that analysis of CPRA data would provide some level of insight into transplant access across the CPRA groups.

There was debate around controlling for post-transplant survival in addition to medical urgency. Some viewed it as a distinct outcome from access, while others felt including it in the request aligned with the composite allocation score (CAS) calculation and could explain differences in access. The presenter from SRTR explained that if post-transplant survival is included, the Committee may be better equipped to discern whether adjustments to the biological rating scales are needed to achieve equitable access.

Potential confounding by transplant program differences, geography, and interactions between biological factors (e.g., height and blood type) were raised as important considerations. The Committee supported examining potential interactions between height & blood type in relation to transplant access. Exploring the multiplicative effects of these factors would provide insight into transplant access for short-statured women with blood type O; a member noted that short-statured women are more likely to have restrictive lung disease.

Committee members inquired if there was a way to pair donor height ranges in 6-month cohorts to better understand the availability of donors for shorter recipients or if in some situations, shorter donors are being allocated to taller recipients. The Committee also asked the SRTR if there was a way to incorporate geography and efficiency into this data request.

Additionally, there was support for excluding data from the first 3 months of lung continuous distribution (CD) as modifications to the blood type rating scale implemented on September 27<sup>th</sup>, 2023 significantly altered transplant access.

Next steps:

The SRTR will write a formal data request based on this discussion, which will be reviewed and approved by Committee leadership.

**2. Offer Filters update**

Lung offer filters were implemented on January 31, 2024. Of 71 active lung transplant programs, 52 have accessed Offer Filters and 16 enabled at least one filter. In total, 41 filters have been enabled across the 16 programs; the most used filter criteria are height and donor distance. The average percentage of offers filtered per program is 22%.

Summary of discussion:

No decisions were made.
-------------------------

The Committee discussed ideas for increasing the adoption of lung offer filters. The use of filters in education and webinars can be helpful for transplant programs, but they may need more concrete examples and prompts to effectively utilize the tools. The community may not be aware of tools available, such as Offer Filters Explorer, which helps programs understand the impact lung offer filters would have, using their own data. Members discussed that individual outreach and one-on-one education may be helpful.

Next steps:

The Committee will periodically review Offer Filters usage data. The OPTN Contractor will continue to explore ways to increase adoption of lung offer filters.

**3. Public comment analysis discussion: *Promote Efficiency in Lung Allocation***

The *Promote Efficiency in Lung Allocation* [proposal](#) was submitted for community feedback from January 23, 2024 to March 19, 2024. There was overall support for the proposal, demonstrated by a sentiment score of 4.0. Sentiment scores by member type range from 3.9 to 4.4. The Committee reviewed community feedback, including the following themes:

- Opt In to Offers from Geographically Isolated Areas
- “Bypass Bilateral and Other Lung” Option
- Proposed New Data Fields
- Recommendations for Donor Information or Offer Filters

Summary of discussion:

No decisions were made.
-------------------------

*“Bypass Bilateral and Other Lung” Option*

The Committee discussed nuances in the allocation process related to a “reverse” option for when an Organ Procurement Organization (OPO) chooses to bypass bilateral lung candidates and the accepting program rescinds offer acceptance. This would allow OPOs to place the organ where it is most needed. It was clarified that whether to utilize the reverse option should be at the discretion of the OPO, rather than required by policy, as the decision requires clinical judgement of factors like donor stability.

*Proposed New Data Fields*

The Committee discussed one comment about the cost benefit analysis of new data collection for History of anaphylaxis to peanut and/or tree nut. While this is a rare event, members felt that it was concerning enough to the community to collect this as discrete data field for future use as an offer filter.

*Recommendations for Donor Information or Offer Filters*

The Committee discussed the merits and challenges of using the community’s suggested data fields as offer filters.

Predicted TLC: Members agreed this could be a useful filter and discussed the need to determine which formula to use for calculating predicted TLC values.

Cigarette use: Concern was raised that cigarette use in pack years may not fully capture smoking history, as it does not account for other inhalants. Members expressed the need for more granular data and interest in developing a filter for cigarette use.

Lung compliance: Members felt lung compliance data would be too variable across institutions and difficult to reliably collect, making it a poor choice for an offer filter. As a potential alternative to lung compliance, members suggested documenting peak airway pressure as it may correlate with lung compliance.

Respiratory viral testing: There was discussion around including viral respiratory infection results (e.g. COVID-19, influenza, RSV) as a potential filter. Members noted some programs would accept donors

with certain viral infections, while others would not. Concerns were raised about uniform availability of testing across donor hospitals.

Sequence on match run: Members inquired about the possibility of using sequence on the match run as a filter, which could help avoid review of organ offers that had already been turned down by many other centers. This capability does not currently exist. However, concerns were raised that such a filter may prevent acquisition of organs that could be viable later in that match run due to changing clinical circumstances.

Epstein-Barr Virus (EBV) & Cytomegalovirus (CMV): EBV and CMV are part of current data collection. The Committee discussed that offer filters for EBV and CMV may be helpful to pediatric transplant programs. There were no pediatric representatives available during the discussion.

#### *Other Considerations*

There was discussion around whether offer filters should be applied universally at the program level or individualized for each candidate. Advantages and disadvantages of both approaches were debated. Ultimately, most members agreed that, ideally, filters should be candidate-specific to account for differences in clinical condition, urgency, and acceptable donor characteristics.

#### Next steps:

On April 25<sup>th</sup>, 2024, the Committee will conclude this discussion and vote to submit the *Promote Efficiency in Lung Allocation* proposal to the OPTN Board of Directors.

#### **4. Promote Efficiency of Lung Allocation Workgroup update**

Since December 2023, the Promote Efficiency of Lung Allocation Workgroup (Workgroup) has reviewed [OPTN Policy 2.11.D](#) and guidance, engaged with OPOs on gaps and pain points, and discussed potential efficiency-focused recommendations. In this meeting, the Committee reviewed Workgroup recommendations for arterial blood gas (ABG) testing, bronchoscopies, chest x-rays, non-contrast computed tomography (CT) scan, echocardiograms, lung measurements, fungal cultures, and ventilator settings.

#### Summary of discussion:

The Committee supported moving CT scan from guidance to policy.

The Committee supported the recommendation for ABG testing to be completed within 2 hours prior to the initial offer(s) on the match run. Most members supported the recommendation for ABGs to be performed every 4 hours following the initial offer(s). Some members supported every 8 hours after organ acceptance.

Members agreed that the initial ABG should be a true challenge gas, but there was mixed feedback on whether each subsequent ABG should be a true challenge gas.

The Committee supported moving CT scan from guidance to policy. Though CT scan images are preferred to interpretations, members discussed challenges obtaining CT scan imaging, including the inability to transmit images from the donor hospital and being unable to view the lung CT windows.

The Committee supported the recommendation for ABG testing to be completed within 2 hours prior to the initial offer(s) on the match run. Most members supported the recommendation for ABGs to be performed every 4 hours following the initial offer(s). One lung transplant surgeon expressed concerns about requiring ABG testing every 4 hours following the initial offer due to the burden on OPOs. A member from an OPO noted that from an efficiency standpoint, requiring ABGs every 4 hours following

the initial offer promotes allocation efficiency by preventing additional requests as OPOs progress through the match run. Concerns were raised about lung recruitment maneuvers being performed every 4 hours ahead of ABG testing during allocation. A lung transplant surgeon commented that such frequent lung recruitment may be injurious. The Committee discussed whether lung protective strategies should be recommended in OPTN guidance.

Feedback on the timeline for ABG testing after organ offer acceptance indicated that transplant programs usually need at least one additional ABG test after acceptance and do not need one every 4 hours after acceptance. There were two suggestions: end required ABG testing upon offer acceptance or reduce the frequency of required ABGs to at least every 8 hours upon offer acceptance. The first suggestion would require the transplant program and the OPO to coordinate any additional ABG testing. The second suggestion would reduce the burden on OPOs while ensuring the accepting program with enough information to identify issues and manage donor lungs.

Regarding ventilator settings for ABG testing, members agreed that the initial ABG, required within 2 hours prior to the initial offer(s), should be a true challenge gas, defined by ventilator settings on 5cm/H<sub>2</sub>O/Positive end expiratory pressure (PEEP) and 100% FiO<sub>2</sub> as outlined in Policy 2.11.D. There was somewhat mixed feedback on whether each subsequent ABG should be a true challenge gas. Some members felt all ABGs should be true challenge gases (current policy) as it would consistently and accurately represent the PaO<sub>2</sub>/FiO<sub>2</sub> (P/F) ratio.

The Committee was interested in exploring a system enhancement that would allow data transfer of ventilator settings entered by OPOs to the offer reviewed by transplant programs. There was discussion around the desire to receive peak inspiratory pressure (PIP), potentially alongside ABG results. However, it was explained that PIP is only clinically meaningful in the context of donor ventilator settings. A member from an OPO reported that currently donor ventilator settings are often reported in the OPTN Computer System. The suggested system enhancement would promote efficiency as less time would be spent manually communicating this information.

Next steps:

The Committee's feedback will be reviewed by the Workgroup.

**5. Expeditious task force update**

The Committee received an update on the Expeditious task force, including comments from task force meetings about lung placement efficiency and multi-organ allocation (MOT) involving lungs. The task force is proceeding with multi-pronged studies to examine organ non-use and allocation out of sequence events and the creation of rescue pathways to increase usage of organs at high risk for non-use.

Summary of discussion:

No decisions were made.
-------------------------

Members discussed issues at the donor hospital level that create barriers to increasing efficiency of lung allocation and to increasing the number of transplants. There was discussion around the lack of incentives for donor hospitals to prioritize time in the operating room for organ procurement. A member commented that decreasing non-use alone may not be enough to increase the number of transplants; the need to expand the donor pool to increase transplants was emphasized.

The Committee discussed differences in OPO behavior related to MOT allocation for lung-liver and heart-lung candidates. Members briefly reviewed options for addressing inefficiencies associated with

lung & liver allocation, such as increasing the CAS threshold. The Chair asked to involve the OPTN Liver & Intestine Committee in future discussions on this topic. Regarding heart-lung allocation, a member from an OPO commented that there may be confusion about [OPTN Policy 6.6.F](#). The policy requires that heart and heart-lung candidates in allocation classifications 1-4 are prioritized for offers on the match run, when the OPO is offering a heart and lung from the same deceased donor. The member stated, "classifications 1-4" is often confused with "status 1-4".

Next steps:

The Committee will re-visit MOT discussions in future meetings.

**Lung Review Board update**

The Committee received an update on Lung Review Board (LRB) operations, including a summary of exception request data from the pre-CD era (3/9/2022-3/8/2023) and post-CD era (3/9/2023-3/8/2024).

Data summary:

- There were twice the number of exception requests submitted post-CD era.
- Group D is most likely to submit exception requests but also largest diagnosis group.
- After the implementation of [Modify Lung Allocation by Blood Type](#) (ABO modification) (ABO modification), exception requests for medical urgency are the most likely to be submitted and approved.

These data will be in the Lung CD One-year monitoring report, which will be available on the [OPTN website](#) in May 2024.

Summary of discussion:

No decisions were made.

Members discussed the need for additional education about exception requests for lung transplant programs. Additional education about the types of candidates for which an exception request may be appropriate may encourage certain programs to submit requests. There was a suggestion to provide the community with examples of helpful narratives that contain all the necessary information to make the best argument for their candidates in the exception request. It was discussed that data showing how many different programs are submitting these requests may help to identify which programs or regions could benefit from additional education.

**Public comment analysis discussion: *Standardize Six Minute Walk for Lung Allocation***

The *Standardize Six Minute Walk for Lung Allocation* [proposal](#) was submitted for community feedback from January 23, 2024 to March 19, 2024. There was overall support for the concept, demonstrated by a sentiment score of 3.8. Notably, there was no opposition from patients and minimal opposition from transplant programs, which are the two member types most impacted by this proposal. The Committee reviewed community feedback, including the following themes:

- Logistical and Financial Considerations
- Recommendations for Guidance
- Altitude Considerations

### Summary of discussion:

No decisions were made.

### *Logistical and Financial Considerations*

The Committee discussed the timing of the oxygen titration test ahead of the initial six-minute walk test. There was agreement with community feedback that an oxygen titration test and a six-minute walk test on the same day would be physically challenging for candidates. Performing the titration test six months ahead of the six-minute walk test was deemed too far in advance; the candidate's oxygen needs may change significantly during this timeframe. Members discussed two other timeframes: 6-12 weeks or 2 days ahead of the initial six-minute walk test. The timeframe of 6-12 weeks may help to mitigate issues with payor reimbursement for testing, though some members reported having no issues with reimbursement when these tests were performed two days apart. Members agreed that additional input is needed regarding reimbursement for services to better understand the financial implications of this proposal.

### *Recommendations for Guidance*

The Committee discussed community feedback that recommended adding guidance for patients on high flow oxygen in an intermediate or intensive care unit (ICU), undergoing urgent waitlist evaluation. Members acknowledged that it is unsafe for such candidates to attempt the six-minute walk test as they cannot be transported to a pulmonary function test laboratory and ICUs are not set up appropriately. Members suggested that zero feet should be entered for these candidates if they are unable to complete the test.

### *Altitude Considerations*

Members acknowledged that there are likely very few programs and candidates affected by altitude. Members discussed recommending that the oxygen titration test and the six-minute walk test be performed at the transplant program to ensure consistency and fairness in allocation. It was noted that it would be difficult to ensure the titration protocol was performed consistently if done at a location other than the transplant program.

### Next steps:

The OPTN Contractor will request feedback from other stakeholders regarding reimbursement considerations related to this proposal. On April 25<sup>th</sup>, 2024, the Committee will conclude this discussion and vote to submit the *Standardize Six Minute Walk for Lung Allocation* proposal to the OPTN Board of Directors.

### **Upcoming Meeting**

- April 25, 2024, 5 PM EST, teleconference

## Attendance

- **Committee Members**
  - Marie Budev
  - Matthew Hartwig
  - Erika Lease
  - Ed Cantu
  - Thomas Kaleekal
  - Soma Jyothula
  - Brian Keller
  - Julia Klesney-Tait
  - Dennis Lyu
  - Jaclyn Russe
  - Lara Schaheen
  - David Erasmus
  - Sid Kapnadak (virtual)
  - Ernestina Melicoff (virtual)
  - Brian Armstrong (virtual)
  - Katja Fort Rhoden (virtual)
  - Errol Bush (virtual)
  - Wayne Tsuang (virtual)
- **HRSA Representatives**
  - Marilyn Levi (virtual)
  - James Bowman (virtual)
- **SRTR Staff**
  - Maryam Valapour
  - Grace Lyden (virtual)
  - David Schladt
  - Nicholas Wood (virtual)
  - Katie Audette (virtual)
- **UNOS Staff**
  - Kelley Poff
  - Kaitlin Swanner
  - Susan Tlusty
  - Chelsea Hawkins
  - Samantha Weiss
  - Delaney Nilles
  - Leah Nunez (virtual)
  - Carlos Martinez (virtual)
  - Sara Rose Wells (virtual)
  - Holly Sobczak (virtual)
- **Other Attendees**
  - Joseph Tusa (virtual; incoming Committee member)