

## **OPTN Lung Transplantation Committee**

### **Meeting Summary**

**April 14, 2025**

**Conference Call**

**Matthew Hartwig, MD, Chair**

**Dennis Lyu, MD, Vice Chair**

### **Introduction**

The Lung Transplantation Committee (Committee) met via Webex teleconference on 4/14/2025 to discuss the following agenda items:

1. Public Comment Analysis & Vote: *Modify Lung Donor Data Collection*
2. Addressing Candidate Biology in Lung Allocation

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

#### **1. Public Comment Analysis & Vote: *Modify Lung Donor Data Collection***

Modify Lung Donor Data Collection was available for OPTN public comment from January 21 to March 19, 2025.

#### Presentation Summary

Purpose of proposal:

- Promote efficiency of lung allocation by updating data collection on lung donors
- Respond to community feedback on tools and data to increase efficiency
- Streamline communication and information sharing between Organ Procurement Organizations (OPO) and lung transplant programs as transplant programs consider lung offers

Rationale:

- Collect additional data to provide information necessary to make informed decisions on lung offers
- Update current data collection to improve accuracy and increase granularity of information used to make informed decisions on lung offers

There was a review of actions to be taken by OPTN members upon implementation of this proposal, and the questions to which the Committee sought community feedback during the Public Comment period.

There was a review of the public comment feedback received on the proposal. The public comment analysis document sent to Committee members prior to the conference call. Public comment analysis themes were broken down by proposed data collection elements.

### Summary of discussion:

The Committee reaffirmed proposed changes related to peak inspiratory pressure (PIP), predicted Total Lung Capacity (pTLC), Cigarette Smoking History, Vape Use History, and Marijuana Smoking History.

The Committee recommended revising *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* to clearly state when PIP must be collected and what ventilator settings must accompany it.

The Committee proposed adding "donor instability" as a selectable reason for OPOs when reporting that a donor diagnostic test could not be completed.

The Committee proposed right heart catheterization (RHC) as an addition to the diagnostic test type dropdown list.

There was a vote to submit the proposal for consideration by the OPTN Board of Directors; votes were as follows, 16 yes; 0 no; 0 abstain.

Upon discussing public comment feedback, the Committee reaffirmed the following as proposed in public comment:

- Its support for collecting PIP rather than plateau pressure (Pplat)
- The addition of acceptable donor pTLC range and data definitions
- Its proposal for the History of Smoking, Cigarette Smoking History, Vape Use History, and Marijuana Smoking History data collection and data definitions
- Its recommendations for the addition of cigarette smoking history data collection and data definitions and the removal of Cigarette Use (>20 Pack Years) Ever data collection

### *PIP*

The Committee revisited its rationale for recommending the collection of PIP as opposed to Pplat. The Committee reaffirmed its support for collecting PIP, citing its accessibility and reliability, as it is obtained directly from the ventilator. In contrast, Pplat was considered more subject to variability, as its measurement can be influenced by differences in interpretation and technique among clinical staff.

In response to feedback requesting greater clarity on the timing of PIP collection and concerns that PIP may be collected in isolation without specific ventilator settings, the Committee recommended revising *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* to clearly state when PIP must be collected and what ventilator settings must accompany it. In the public comment proposal, the Committee stated that, "Upon implementation of Promote Efficiency of Lung Donor Testing, *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* would require the PIP to be reported with the ventilator settings at the same frequency as [arterial blood gases (ABG)]." This means that whenever an ABG is required in the policy, PIP must also be collected and reported, along with the relevant ventilator parameters.

### *Diagnostic Test Status data collection*

It was noted that, while many stakeholders supported the intention of collecting diagnostic test statuses to improve transparency and decision-making, technical and workflow challenges were raised. Some respondents agreed that without real-time notifications, transplant programs would still rely on manual updates from OPOs (calls, emails, notes). They recommended the addition of such notifications to the policy's implementation. Some OPO stakeholders noted that because the diagnostic test type dropdown does not include RHC, they will use angiography to record a RHC result.

During discussions regarding the potential inclusion of automatic electronic notifications for diagnostic testing status updates, the Committee learned of a broader, OPTN-approved project that is expected to address this issue more comprehensively. Led by the OPTN Operations and Safety Committee, this project aims to re-evaluate deceased donor testing requirements for all organs except lung, with the goal of promoting greater efficiency in the organ offer process. As a result, the Committee agreed that the scope of the current project should not be expanded to include electronic notifications and that this issue would be more appropriately addressed in coordination with future notification standards applicable across all organs.

As a post-public comment revision, the Committee proposed adding "donor instability" as a selectable reason for OPOs when reporting that a donor diagnostic test could not be completed. The Committee clarified that this option should be used when a donor is too unstable for diagnostic testing. To ensure accurate data recording, RHC is being proposed as an addition to the diagnostic test type dropdown list.

### *Addressing feedback on Uniform Donor Risk Assessment Interview (UDRAI)*

Lastly, it was clarified that the OPTN does not own the UDRAI, and therefore it is outside the scope of this policy to directly update the form. However, the Committee recommends that the OPTN collaborate with the American Association of Tissue Banks (AATB), the Association of Organ Procurement Organizations (AOPO), and the Eye Bank Association of America (EBAA) to consider updates to the UDRAI.

### *Committee Vote*

The Committee reviewed the proposal, including post-public comment changes. There was a vote to submit the proposal for consideration by the OPTN Board of Directors; votes were as follows, 16 yes; 0 no; 0 abstain.

### Next steps:

The Committee will submit proposed policy language, data collection and data definitions for consideration by the OPTN Board of Directors.

## **2. Addressing Candidate Biology in Lung Allocation**

The Committee has expressed support for considering alternate approaches for incorporating candidate biology into lung allocation. This topic was last discussed on February 27, 2025.

### Presentation summary

#### *Supply-adjusted model*

The presenter provided an overview of a supply-adjusted model, which assigns up to 10 points based on the candidate's projected access to compatible donors, using a combined measure of height and blood type. The model seeks to improve upon current lung composite allocation score (CAS) adjustments by aligning point distribution with empirically estimated disparities in donor access. The presenter

emphasized that disparities related to candidate height have historically been more pronounced than those associated with blood type, and that the new model may mitigate these imbalances.

### *Size-Matching Rating Scale Based on Offer Acceptance Behavior*

Following the presentation and discussion of the supply-adjusted model, a representative from Scientific Registry of Transplant Recipients (SRTR) introduced an alternative approach to modeling size compatibility based on historical offer acceptance behavior rather than candidate height alone. This method proposes assigning points based on how often donor-recipient size combinations result in actual transplants, offering an empirically grounded alternative to fixed height ranges.

### Summary of discussion

The Committee decided that changes to how CPRA is incorporated into lung CAS would be out of scope for this effort, due to limitations with CPRA data.

Committee members raised questions about the relative improvement in disparity scores about how the results appeared to show less variation in blood type points yet better overall outcomes. The presenter clarified that while blood type-related disparities are addressed, the largest gains in equity were due to reductions in height-related disparities. The new model accounts for the interaction between height and blood type, allowing for more nuanced prioritization.

One member observed that the blood type-modified CAS may have unintentionally overcorrected for blood type without adequately addressing other access factors and questioned whether the supply-adjusted model may slightly disadvantage blood type O candidates. The presenter responded that the empirical model avoids assigning fixed points to specific blood types or heights and instead evaluates the overall supply of compatible donors based on each candidate's unique profile.

Several members expressed concerns about the potential impact of increasing the weight of the height and blood type components beyond the current 10-point maximum. They noted that doing so could affect the balance of the other CAS attributes and may produce unintended outcomes. A member stated that while the current approach offers a promising incremental improvement, broader changes would require additional modeling and evaluation. Another member emphasized the need to consider how the model interacts with other underutilized CAS attributes, such as prior living donor status or pediatric priority.

The SRTR representative outlined the capabilities of a new policy optimization tool being developed in collaboration with Massachusetts Institute of Technology (MIT). This tool will allow simulation of tens of thousands of policy variations and could be used to test both the supply-adjusted model and other alternatives, including adjusted weighting schemes.

### *Data Limitations and Sensitization (CPRA)*

The committee also discussed data limitations, particularly regarding candidate sensitization (CPRA). A member noted that the lack of complete and standardized CPRA data has significantly hindered efforts to include this attribute in lung allocation modeling. The presenter and collaborators confirmed that CPRA data was missing for the majority of lung transplant candidates at the time of analysis. They noted that while statistical imputation and modeling could offer workarounds, the differences between lung and kidney populations make direct transfer of assumptions problematic.

Members discussed whether it would be feasible to model CPRA impact based on population-level human leukocyte antigen (HLA) distributions, thereby allowing for indirect inclusion of sensitization in donor supply estimates. Others noted that without a mandate for programs to report CPRA or

unacceptable antigens—even when zero—the data would remain incomplete. It was also noted that variability in testing practices across centers further complicates standardization. Ultimately, the Committee decided that changes to how CPRA is incorporated into lung CAS would be out of scope for this effort, due to limitations with CPRA data.

### *Alternative Size Matching Approaches*

Following the primary discussion, a representative from SRTR introduced an alternative approach to modeling size compatibility based on historical offer acceptance behavior rather than candidate height alone. This method proposes assigning points based on how often donor-recipient size combinations result in actual transplants, offering an empirically grounded alternative to fixed height ranges.

Members found the concept promising and discussed the possibility of further refining how size compatibility is measured within the CAS. Some members emphasized the importance of considering metrics such as pTLC instead of height alone. It was acknowledged that height-based thresholds used in practice are often based on subjective or center-specific norms, and that a probabilistic model based on real-world acceptance patterns may offer better fidelity.

The presenter shared results from a sensitivity analysis that tested expanded height matching ranges. The results showed minimal change in transplant rates and a modest increase in waitlist deaths, though still favorable compared to existing models. These findings supported the robustness of the proposed approach even under variable clinical assumptions.

### *Committee Feedback and Potential Next Steps*

Committee members expressed strong support for continuing to explore the supply-adjusted CAS methodology within the existing 10-point limit. Several emphasized the need for further simulations using the SRTR/MIT policy optimization tool and recommended examining interactions with other CAS attributes. There was agreement that any expansion of the biological disadvantage score or incorporation of CPRA would require improved data collection and additional research.

The Committee appreciated the modeling team's responsiveness and the data-driven nature of the proposed rating scale. Members agreed that next steps should include further modeling under various assumptions and additional analysis of attribute usage across the candidate population, if the methodology is pursued as a policy proposal.

#### Next steps

The Committee will bring the project forward to Policy Oversight Committee for consideration on May 8, 2025.

#### **Upcoming Meetings**

- May 8, 2025, teleconference, 5PM ET

## Attendance

- **Committee Members**
  - Matthew Hartwig
  - Dennis Lyu
  - Marie Budev
  - Brian Keller
  - David Erasmus
  - Thomas Kaleekal
  - Heather Strah
  - Wayne Tsuang
  - Jody Kieler
  - Ernestina Melicoff
  - Jackie Russe
  - Gary Schwartz
  - Jordan Hoffman
  - David Erasmus
  - Lara Schaheen
  - Stephen Huddleston
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Maryam Valapour
  - Katie Siegert
  - Maria Masotti
  - Nick Wood
- **UNOS Staff**
  - Kelley Poff
  - Kaitlin Swanner
  - Sara Rose Wells
  - Chelsea Hawkins
  - Samantha Weiss
  - Holly Sobczak
- **Other attendees**
  - Johnie Rose (guest presenter)
  - Paul Gunsalus
  - Carli Lehr
  - Jodi Bell
  - Samantha Baker