OPTN Lung Transplantation Committee
Meeting Summary
November 17, 2025
Conference Call

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

Introduction

The OPTN Lung Transplantation Committee (the Committee) met via teleconference on 11/17/2025to discuss the following agenda items:

1. Review simulation modeling and discuss proposed policy
2. Discuss transition plan and policy evaluation plan
3. Review policy language
4. VOTE: Does the Committee recommend this proposal for review by the OPTN Board of Directors?

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

1. Review simulation modeling and discuss proposed policy

The Committee discussed the following simulation results:

- Efficiency rating scale
  - #1- drop to 50% of the efficiency points between 400 nautical miles (NM) and 1,000 NM.
  - #2 - drop to 25% of the efficiency points between 400 NM and 1,000 NM.
  - #3- extended drive zone to 100 NM with drop to 25% if the efficiency points between 400 – 1,000 NM.
- Medical urgency rating scale
  - Current rating scale (base 25 nonlinear curve)
- Varied placement efficiency weights and reduced weights on other attributes proportionally

<u>Data summary:</u>

- Rating scale option 1
  - Adds a steeper drop in efficiency points between 400–1000 NM.
  - At 18% efficiency weight:
    - Median centers in top 25 sequences drops 16 → 14.
    - Travel distance drops by ~100 NM.
    - No significant rise in blood type O transplant rates.
    - Waitlist mortality remains stable up to ~18%.
- Rating scale option 2
  - Larger point drop between 400- 1000 NM (to 25%)
  - At 15% efficiency weight:
    - Median centers in top 25 sequences decreases to 14.
    - Travel distance ~100 NM shorter
    - Minimal change in blood type O transplant rate.

        - Slight waitlist mortality increase but within confidence intervals.
    - Shows least penalty to pediatrics compared to Options 1 and 3.
- Rating scale option 3
    - 100% efficiency points for first 100 NM ("extended drive zone").
    - Even at current weight (10%), waitlist mortality begins trending upward.
    - Still reduces travel ~100 NM and reduces median number of centers in the top 25 sequences slightly (16→15).

  Comparative data across the current rating scale and rating scales 1, 2, and 3
    - Scales 1 and 2 result in only a slight increase in **waiting list mortality** trends, remaining within confidence intervals and indicating minimal change. In contrast, rating scale 3, particularly at a placement efficiency weight of 10%, exhibits a more noticeable change in mortality rates.
    - The **median number of** transplant programs in the top 25 sequences was 14 for rating scales 1 and 2, and 15 for rating scale 3.
    - Similar reduction in **median travel distance** across rating scales 1, 2, and 3.
    - **Transplant rates for blood type O** remain relatively unchanged across different rating scales, likely because this blood group represents a large portion of the population, making it less affected by adjustments to placement efficiency.
    - **Transplant rate by candidate height** indicates that the shortest candidates consistently experience lower transplant rates. Across the three rating scale options analyzed, there may be slight decreases in transplant rates for these shortest candidates.
    - Differences in **transplant rates between pediatric and adult populations** may be influenced by short stature, which could contribute to a slight decline in rates. The decline appears to be least pronounced when using rating scale option 2 with a 15% efficiency weight.

Summary of discussion:

No decisions were made.

Upon reviewing data by month, a member observed a recent decline in allocation out of sequence (AOOS) and suggested that heightened focus on the issue may have impacted Organ Procurement Organization (OPO) practices. The member recommended that the Committee postpone a policy change recommendation until additional time has passed, allowing for further evaluation of this developing trend. A representative from HRSA said continuous distribution was implemented to facilitate adjustments addressing identified challenges within the transplant allocation system. A representative from SRTR acknowledged the existence of efficiency issues in the current system, noting that programs must travel greater distances to procure lungs. However, they also cautioned that the solution currently under discussion may result in unintended consequences, potentially diminishing the value of other parts of the allocation score, such as the points the Committee has assigned to address biological disadvantages. An attendee suggested that, to mitigate the potential unintended consequences mentioned, additional policy modifications may be evaluated moving forward. One member observed that graphs provided by HRSA indicated a temporary decrease in compliance whenever policies changed within any organ system. They explained that this dip might be due to the time needed for the transplant community to adapt to new procedures.

The Vice Chair noted that although the Committee's efficiency policies have Board approval, they are not yet implemented. Some OPOs have improved efficiency through staff expansion and better list management, decreasing out-of-sequence placements, while others continue to struggle with frequent

AOOS. The Vice Chair questioned whether to address AOOS issues now or wait to assess ongoing trends. Members preferred monitoring trends and understanding AOOS causes, including unavoidable late turndowns.

When reviewing the simulated transplant rate vs weight on efficiency attribute for rating scale option 1, the Vice Chair noted that generally, increasing efficiency weighting significantly reduces transplant rates for disadvantaged groups, specifically blood type O. However, at 18% efficiency weight, the rate remains stable.

When discussing for the simulated transplant rate by candidate height, an SRTR representative noted that shorter transplant candidates already face access challenges, which disproportionately affect women, creating both height and sex disparities in access. When combined with factors like blood type O, these disparities multiply rather than exist separately. They further emphasized that the Committee should exercise caution to avoid exacerbating existing disparities when proposing changes. An attendee suggested prioritizing smaller organs for shorter candidates as a potential strategy. A representative from the OPTN Board of Directors (BOD) confirmed that it is feasible to pursue a separate initiative to adjust the weighting for short-statured candidates, and that the current efficiency effort does not prevent the Committee from recommending such changes at a future date.

One member noted that simulation results indicated all three rating scale options would lead to a slight reduction in pediatric transplant rates. The member further observed that AOOS allocations primarily occur early in the matching process and are more frequent when a higher number of unique transplant centers appear among the first 25 sequences. They pointed out that these two observations are not entirely consistent, highlighting the complexity of factors influencing AOOS. The Vice Chair responded that when an OPO encounters an extensive match list, they may opt to expedite organ placement rather than exhaust each option, as the process can become time-intensive and complicated. This logistical challenge may result in increased out-of-sequence placements, particularly when many centers are included among the top 25.

A member noted that after the initial offer notifications, each center has one hour to reply. Afterwards, every center gets 30 minutes for each potential transplant recipient (PTR), even if multiple PTRs are registered at the same center. Therefore, working through the PTRs in the top 20 sequences could take at least 11 hours, regardless of how far apart the centers are or how they are distributed. The member continued that the current approaches appear to mitigate symptoms rather than address the underlying systematic challenge, which they believe has not been comprehensively considered. Other members agreed and expressed a preference to monitor an additional 3–6 months of data before making any recommendations, as these simulations indicate there could be less favorable outcomes for candidates who are short in stature or pediatric. A member noted the limited timeframe for making changes, pointing out that fast-paced updates might require additional modifications to resolve unexpected problems. Furthermore, the present system has effectively reduced mortality rates among individuals on the waiting list. The member said they think there has to be a certain percentage of organs placed out of sequence to prevent nonuse.

A member commented that the Committee has spent over a year developing more efficient allocation methods, all of which have been thoroughly vetted and are ready to implement. This member supported moving forward with the Board-approved changes, as Committee has addressed efficiency concerns by providing transplant centers with the necessary information to streamline decisions and processes.

An HRA representative noted that the system's benefits are unclear, as improvements can't be solely linked to it. The HRSA representative said evidence shows compliance has declined where the system

has had a larger effect, particularly in the Northeast and Midwest, unlike the West where allocation changes were minimal. The HRSA representative said that ongoing evaluation and policy adjustments like those by OPTN and the Committee are crucial for effective governance. A member raised concerns about the lack of data to substantiate the assertion that OPOs allocate organs out of sequence due to local center growth and easier organ placement. Furthermore, they observed that compliance has improved over the past two months without changes to the system.

The Vice Chair noted that while policy changes can address factors like short stature or blood type, it's more challenging to solve systemic issues through policy. Attempting to do so may unintentionally disadvantage certain groups by increasing waitlist mortality or reducing transplant rates. The primary concern of the Committee is to assess whether the potential policy changes represent an appropriate course of action considering the associated risks.

An SRTR representative agreed with the HRSA representative that there is a correlation between AOOS organ placement and broader geographic sharing across all organs. However, increasing the weight of efficiency in the current system may worsen allocation out of sequence by reducing access for candidates who are short or have blood type O, as centers would need to compensate for their decreased access.

A member asked HRSA for a recommended timeline to reassess the effect of a policy modification. The HRSA representative replied that data-backed results would take about two months because OPOs have 30 days to close out their match runs and report that information to the OPTN. The goal would be to observe if the change improves outcomes in areas where the policy is applied, without negatively impacting any groups. They added that the OPTN now faces legal liability, leading to more funds being diverted from patient benefit to cover growing legal expenses. From the perspective of the government, allowing or encouraging legal liability within the system is considered intolerable. The HRSA representative said that is why these issues have been the focus of our conversations during the past six weeks.

A member asked whether it would be acceptable to reverse a policy change if harm to a specific patient population is identified within two months. An attendee responded that it is possible to either withdraw the policy or adjust another aspect of it. A member inquired about the expected timeframe for observing the real impact of these policies on waitlist mortality, as the major drawback of such proposals is that more individuals may die while waiting for a transplant.

2. Discuss transition plan and policy evaluation plan

Summary of discussion:

Vote 1: Does the Committee recommend modifying lung allocation with one of the options presented? 12- Option #4, no change to efficiency score pending monitoring period.

The Committee reviewed a possible evaluation plan for implementing a policy change, which includes monitoring wait list removals. While deaths must be reported within 30 days, removals from the wait list are known almost immediately. Some trends may take longer to detect due to small sample sizes in certain subgroups. An SRTR representative pointed out that overall waitlist mortality rates for transplant candidates are typically low, making it difficult to observe statistically significant changes resulting from policy adjustments within a short timeframe. They further explained that when access to transplantation is restricted, waiting times increase and health risks escalate. Consequently, patients may reach transplantation in significantly worse condition. The representative cautioned that the waitlist mortality

metric may not fully capture these shifts, and with only limited simulation data available, it remains challenging to accurately predict the policy's total impact.

A HRSA representative stated that organ shortages are a widespread issue, not just for lungs, meaning some patients may die or become very ill before receiving transplants. The OPTN aims to ensure organ allocation is orderly and rational rather than arbitrary. The HRSA representative said that the model data is from 2024 when about 15% of lungs were allocated out of sequence and the estimated change in waitlist mortality is small so some of this is speculative. Moving forward, it's important to monitor outcomes closely and respond accordingly using available systems, while considering potential unintended consequences like increased waiting times and mortality rates.

A member asked whether it was possible to recommend no policy change and take no action at this time. The Vice Chair responded that, given their specialized knowledge and experience, the Committee should make the recommendation they determine to be most appropriate. They added that if the Committee decides to take no action, they should also choose one of the rating scale options presented today as a backup.

A patient representative raised concerns about the uncertainty of the proposed policy's effects and the risk of negative outcomes for patients. They emphasized the need to prioritize patient safety and recommended adding a monitoring period to the policy, allowing the Committee to evaluate the real-world effects before making permanent changes. Implementing policy adjustments without careful oversight, they cautioned, could pose unnecessary risks to patients. A representative from HRSA responded that non-compliance with OPTN policy regarding AOOS is a prevalent concern, as HRSA data indicates approximately 90% of patients on the waitlist have been impacted. This issue affected one in five organs last year, with more than one patient being affected per organ. A member noted they do not know if skipping a candidate due to AOOS raises their risk of death or removal from the waitlist under current versus proposed policy and requested supporting data to weigh risks and benefits.

The Vice Chair asked the Committee to recommend one of the following options:

- Rating scale #1, weight of 18%
- Rating scale #2, weight of 15%
- Rating scale #3, wight of 10%
- #4 no change to efficiency score pending monitoring period

Twelve members recommended option #4, no change to efficiency score pending monitoring period. The Committee did not discuss a transition plan as the Committee did not recommend a policy change.

3. Review policy language

The Committee did not review policy language as the Committee did not recommend a policy change.

4. VOTE: Does the Committee recommend this proposal for review by the OPTN Board of Directors?

Summary of discussion:

Vote 2: If the Committee were required to choose, which of the three rating scale options would they select? 9- Rating scale #2, weight of 15%, 3- Abstain.

The Vice Chair subsequently requested that the Committee recommend one of the three rating scales presented during the meeting as an alternative should the OPTN BOD deem action necessary.

Nine members selected rating scale #2, weight of 15%, as the best option of the three options considered. Three members elected to abstain.

Next steps:

The OPTN BOD will review the Committee's recommendations and vote during their meeting on November 20, 2025

Upcoming Meeting

- December 11, 2025, 5-6pm ET

Attendance

- **Committee Members**
  - Dennis Lyu
  - Marie Budev
  - Matt Hartwig
  - David Erasmus
  - Jody Kieler
  - Ernesta Melicoff-Portillo
  - Wayne Tsuang
  - Heather Strah
  - Brian Keller
  - Siddhartha Kapnadak
  - Katja Fort Rhoden
  - Brain Armstrong
  - Jackie Russe
  - Thomas Kaleekal
  - Joseph Tusa
  - Jordan Hoffman
- **HRSA Representatives**
  - Raymond Lynch
  - Sarah Laskey
- **SRTR Staff**
  - Maryam Valapour
  - Katie Siegert
- **UNOS Staff**
  - Kaitlin Swanner
  - Kelley Poff
  - Keighly Bradbrook
  - Susan Tlusty
  - Houlder Hudgins
- **Other Attendees**
  - John Magee
  - Doug Fesler
  - Peter Nicastro
  - Bill Ryan
  - Andrew Courtwright
  - Elijah Pivo
  - Thomas Athey