

**OPTN/UNOS Thoracic Organ Transplantation Committee
Meeting Minutes
July 19, 2018
Conference Call**

**Ryan Davies, MD, Chair
Erika Lease, MD, Vice Chair**

Introduction

The Thoracic Organ Transplantation Committee met via Citrix GoToTraining teleconference on 07/19/2018 to discuss the following agenda items:

1. Modifications to the Distribution of Adult Donor Lungs – 6 Month Monitoring Report
2. Eliminate the Use of DSAs in Thoracic Distribution – Kick Off

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

1. Modifications to the Distribution of Adult Donor Lungs – 6 Month Monitoring Report

UNOS Research staff presented the 6 month report on the emergency policy change to remove DSA as a unit of allocation. This policy change was implemented on November 24, 2017.

Data Summary

Below is the executive summary of the report which is available on the OPTN website¹:

Monitoring began upon implementation of the emergency action lung policy change on November 24, 2017. The primary goal of the policy was to address concerns over compliance with the OPTN Final Rule.

Based on the first 6 months of data collection post policy:

- An expected change was seen in the distribution of match lung allocation score (LAS) at transplant for recipients. As predicted there was an increase in the mean match LAS at transplant. This change and its magnitude varied across OPTN regions.
- An increase was seen in the median distance between donor hospital and transplant center and a decrease in the number of local lung transplants. However, the majority of lungs are allocated within the first unit of allocation (250 NM radius from the donor hospital).
- There was a decrease in deceased donor utilization nationally, but the impact varied by OPTN region.
- The national discard rate increased, but varied by OPTN region.
- Nationally there was an increase in ischemic time and time from first electronic offer to cross clamp.
- The number of additions to the lung waiting list increased. However, the cohort does not show evidence of change with respect to diagnosis group, match LAS at listing, or removals due to too sick to transplant or death.
- Nationally there was an increase in the number of lung alone transplants, but this varied by OPTN region.
- Nationally there was an increase in the number of DCD donors.

¹ https://optn.transplant.hrsa.gov/media/2517/20180621_thoracic_Committee_report_lung.pdf

- The recipient cohorts do not show evidence of a difference across eras with respect to diagnosis group, procedure type, or ABO.

The conclusions from the 6 month report predominantly align with those from the earlier 4 month report. However, it is still early post-implementation. Changes such as those to behavior or clinical practice may have an impact on the system. The implications of the policy change will continue to be monitored closely with regular reports to the Thoracic Committee.

Summary of Discussion

One Committee member asked about the impact on smaller centers. UNOS Research staff noted that some of the smaller centers have seen a decrease in the number of transplants, although most transplant center volumes have done equal or more transplants. Additionally, the overall number of lung transplants have increased which obviously impacts the numbers.

One Committee member asked if there was any correlation between the increase in DCD lungs and the increased use of Ex Vivo Lung Perfusion (EVLP). The rationale being that some centers might be more willing to accept DCD donor lungs if EVLP is available. UNOS Research staff agreed to look into the data. One Committee member commented that Region 10 has the greatest increase in the use of EVLP lungs.

One Committee member asked if there was a correlation between the use of EVLP and the discard rate. UNOS Research staff noted that the discard rate ranges from 4-8% for lungs. It is possible that any increase in discards might be attributed to EVLP since, according to OPTN data, approximately 50% of lungs undergoing EVLP are discarded. Another Committee member asked if a double lung that undergoes EVLP but only results in a single transplant is counted as a transplant or discard. UNOS Research staff agreed to get the answer to this question.

One Committee member commented that it is interesting to see that there were more transplants, however the number of Group D patients being transplanted did not increase despite the higher LAS. He also noted that the data on utilization rates show that Region 9 has one of the lowest rates while Region 10 has one of the highest. The Committee chair asked if there was a way to risk adjust the utilization data based on OPO recovery rates. For example, a particular OPO might aggressively pursue liver donors and that might impact lung utilization unless they are equally aggressive at pursuing lung donors.

2. Eliminate the Use of DSAs in Thoracic Distribution – Kick Off

The Committee Chair provided an overview of the plan to eliminate the use of DSAs in thoracic distribution. The reason for making this change is a preemptive action to:

- Protect the transplant community's decision-making ability by revising policy with a replacement for the use of DSA as quickly as possible
- Ensure that decisions are data-driven and include community input on changes to allocation policy by following as much of our regular process as possible

This will be a coordinated effort and approach across the organ-specific Committees in order to ensure consistency. There will also be oversight from and collaboration with the Ad Hoc Geography Committee. Committee leadership will provide regular reports to the Geography Committee.

Committee leadership noted that the goal is to come up with a “better system” in order to meet the short timeline for aligning allocation policies with the OPTN Final Rule. The “ideal system” is one that will take a lot more work and time to accomplish. Committee leadership recommended eliminating DSA and keeping the fixed distance circles that we currently have since they have been extensively analyzed. The Committee can work to replace DSA with a distance that results in a positive (or at least neutral) impact to the following:

- Number of transplants
- Waitlist mortality
- Utilization

Committee leadership noted that the decisions must be consistent with the Final Rule and the principles of geography and the Committee must provide a rationale for their recommended changes.

Committee leadership outlined the scope of the work which includes:

- Adult heart distribution – What distance should replace DSA?
- Pediatric heart distribution
- Adult lung distribution – Do we want to change 250 nautical miles to match heart and/or do something different?
- Pediatric lung distribution
- LAS threshold to distribute more broadly – to be determined (TBD) whether in scope

Summary of Discussion

The Committee members generally agreed that fixed distances make the most sense but decisions regarding heart and lung should be evaluated separately based on data. One Committee member noted that cold ischemia time (CIT) is shorter for heart and there is ELVP for lungs that might impact the mileage.

The Committee members agreed that cost and transportation are factors that need to be considered. It is obviously more expensive to rent a plane. While an analysis of the lung system only shows an increase in distance by 50 miles, some transplant hospitals have anecdotally described a significant increase in cost. UNOS staff noted that the Committee cannot limit distance based on cost alone but it can be part of the discussion. UNOS staff requested that if any Committee member has data on transportation and costs it would be helpful since the Scientific Registry of Transplant Recipients (SRTR) has a limited amount of data that was used for the liver discussions. UNOS staff noted that the Liver Committee has identified 150 miles as the metric for when driving becomes flying.

One Committee member asked if 250 miles was part of the modeling for the new heart allocation system. UNOS staff noted that the geographical modeling for heart did not include that distance. SRTR staff noted that one of the earlier models called “share all” looked at 4 different schemes, including one that did not include DSAs. They noted that the data is available and was provided to the Committee as part of the meeting materials.

One Committee member commented that there needs to be an awareness of potentially disadvantaging certain patient populations, such as highly sensitized patients, with any changes proposed by the Committee.

UNOS staff asked the Committee if there were any pre-public comment collaboration needed with groups that might not support larger units of distribution. For the lung proposal, the ISHLT² supported 250 miles as the first zone of distribution but had concerns about a larger radius and its impact on CIT and post-transplant outcomes. One Committee member noted that EVLP is not available for pediatrics. Committee members noted that broader sharing to Zone A already exists in pediatric heart allocation although DSAs are included. One Committee member commented that it would be interesting to know the average distance traveled for pediatric hearts.

² The International Society for Heart & Lung Transplantation

UNOS staff highlighted the principles of geographic organ distribution as well as the timeline. The Committee was reminded that deceased donor organs are a national resource to be distributed as broadly as feasible and the Committee will need to determine how broadly to distribute hearts and lungs. The goal is to have a final data request submitted to the SRTR by August 30, 2018. This will require additional conference calls during July and August.

Upcoming Meeting

- July 26, 2018 (Conference call)