

OPTN/UNOS Thoracic Organ Transplantation Committee
Meeting Summary
September 18, 2014
Chicago, Illinois

Joe Rogers, MD, Chair
Kevin Chan, MD, Vice Chair

Discussions of the full committee on September 18, 2014 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.

Committee Projects

1. Heart-Lung Allocation

For several years, the Committee has worked to clarify Policy 6.5.E: Allocation of Heart-Lungs to reduce the vagueness of the policy and to help OPOs consistently allocate heart-lung blocks. With the help of the OPO Committee, the Committee created a guidance document that can be used by OPOs nationwide to adopt a uniform approach for allocating heart-lung blocks. The Thoracic Committee voted to recommend the guidance document for consideration by the Board of Directors (17 support, 0 oppose; 0 abstentions).

The Committee also discussed distributing a policy proposal, consistent with the guidance document, during the January 2015-March 2015 public comment cycle. In the future, the Committee plans to incorporate the heart-lung allocation policy into the new adult heart allocation policy to balance the urgency of both heart and lung candidates.

2. LAS of 50 and Higher

The Board of Directors previously approved the proposal to require lung transplant programs to report three LAS variables (PCO₂, Assisted Ventilation and Supplemental Oxygen) every 14 days for lung candidates with an LAS of 50 or higher. Though the policy was implemented on February 1, 2012, the UNOS Department of Evaluation and Quality (DEQ) cannot monitor the policy adequately due to ambiguity in the policy language. The Thoracic Committee worked with DEQ to clarify the policy language to reflect the original intent of policy and allow effective DEQ monitoring. The Thoracic Committee voted to recommend clarifications of the policy language for consideration by the Board of Directors (17 support; 0 oppose; 0 abstentions).

3. Ex Vivo Lung Perfusion (EVLN)

Following an extensive evaluation, the Thoracic Committee previously decided to retain current lung allocation policy after the introduction of EVLN technology. DEQ monitoring of lung allocation will be imperative to ensure compliance with the policy following the introduction of EVLN. Instead, the Thoracic Committee focused on the data elements that may need to be collected in order to monitor the use of EVLN for deceased donor lungs.

A modified version of the Deceased Donor Registration form (DDR) will be used beginning in the Spring of 2015. The new lung DDR will include fields for left lung machine perfusion and right lung machine perfusion, with an option of selecting yes or no for each. The Thoracic Committee discussed these fields and recommended a slight modification to the field description to capture the intent to use machine perfusion to optimize donor lung function prior to transplantation.

The Thoracic Committee noted that even if EVLP utilization is captured on the DDR, there will be an information gap on the use of EVLP at the time of transplantation. Therefore, the Thoracic Committee may develop additional fields to include on either the Transplant Recipient Registration form (TRR), or upon Waitlist removal, to ensure that the OPTN is capable of capturing all instances of EVLP. Any recommended changes to the TRR will be circulated for public comment once developed.

The data collection element of this project must first be approved by the Policy Oversight Committee (POC), which meets on October 20-21, 2014. Additionally, the OPTN/UNOS Membership Department has formed a work group to specifically look at membership issues related to companies that provide organ perfusion services.

Committee Projects Pending Implementation

4. Lung Allocation Score (LAS) Modification

OPTN/UNOS IT staff is currently programming the LAS policy modifications approved by the Board in November 2012, but has identified issues in the approved policy language that prevent an accurate LAS calculation, including language describing the waiting list mortality measure, the post-transplant survival measure, and the threshold change and threshold change maintenance calculations for bilirubin, serum creatinine, and PCO₂. In order to ensure that the LAS calculation is correct, the Thoracic Committee voted to recommend modifications to the policy language for consideration by the Board of Directors (17 support; 0 oppose; 0 abstentions). The recommended modifications also include edits for clarity and corrections to plain language rewrite transitional errors. The project is on schedule to be implemented by the end of February 2015.

Review of Public Comment Proposals

5. Definition of Pancreas Graft Failure

The Pancreas Committee presented its proposal to define pancreas graft failure to the Thoracic Committee. The Pancreas Committee sought feedback on whether a general definition of graft failure is appropriate for all organs, or whether there should be an organ-specific definition defined by each organ-specific committee. The Thoracic Committee determined that the general definition of graft failure is not entirely applicable to the thoracic organs as currently written in policy, and believes that each organ most likely requires a different definition of graft failure.

Other Significant Items

6. Review Board Guidance

Recently, members of the heart regional review boards (RRB) and Lung Review Board (LRB) have reached out to Thoracic Committee leadership seeking guidance for

decision-making. Thoracic Leadership has also noticed variability between regions, and noted that some review board members' decisions are quite prescriptive. The review board guidelines focus primarily on review board operations, rather than on how the review board members should make decisions. The Thoracic Committee is concerned that the disparity in decisions is also a problem of equity, as cases in different regions are treated differently.

The Committee noted the factors that may lead to such disparity. There is tension when serving on the RRB because the member is judging other programs within his or her own region. The member may either feel uncomfortable denying a case (for fear that a member's case may be denied in turn) or may feel undue pressure to approve a case (in the hopes the member's cases will also be approved).

The Committee brainstormed potential solutions. One idea may be to send cases from one region to another RRB, so an RRB member is never reviewing cases originating from his or her region. Another solution may be to develop "super-regional" review boards, combining two or three RRBs together, or even one national heart review board. Other suggestions include sending a letter to the review board members reminding them of their duties, or to have a more stringent training program.

The Thoracic Committee leadership will continue to discuss this problem and potential solutions and bring a proposal to the next full Committee meeting.

7. Domino Donors

The Living Donor Committee is drafting a policy proposal to clarify the living donor status of a domino donor. In the past, domino donor heart transplants have been performed, though none have occurred since 2006. Therefore, the Living Donor Committee sought early feedback from the Thoracic Committee regarding its proposal. The Thoracic Committee approved the concept and policy language proposed by the Living Donor Committee, with suggestions regarding the clarity and intent of the policy language.

8. Primary Graft Dysfunction in Heart Transplant Recipients

The Membership and Professional Standards Committee (MPSC) sent the Thoracic Committee a letter inquiring whether additional data related to immediate graft dysfunction should be added to the Transplant Recipient Registration form (TRR) or Transplant Recipient Follow-Up form (TRF) for heart recipients. The MPSC specifically asked whether the OPTN should collect data to capture graft function immediately after implantation, and if so, which data elements are needed to define and assess graft dysfunction. Additionally, the MPSC asked whether programs should be required to report immediate graft dysfunction that may or may not result in graft failure. The goal of the data collection would be to determine whether there are factors that contribute to a potentially higher incidence of primary graft dysfunction (PGD) in transplant programs across the country.

The Thoracic Committee reviewed the current and future data collection fields on the TRR and TRF and determined that they are not adequate to capture PGD because the forms only capture failure or function, with no middle ground for dysfunction with mechanical support. Though the Committee determined that current data collection is inadequate to capture PGD, it did not agree upon a definition of PGD or additional fields

that would help identify PGD. It submitted a data request to review 30-day post-transplant mortality rates for the last three years, broken into six-month intervals. These data will be presented to the Heart Subcommittee at a future meeting.

9. Staged Lung Transplantation

The Thoracic Committee discussed the policy implications of an abstract published in April 2014 entitled, “Is a Priori Staging of Bilateral Lung Transplant the Optimal Surgical Approach for High-risk Patients With Interstitial Lung Disease?”¹ The abstract presents a surgical strategy for candidates requiring a double-lung transplant due to interstitial lung disease. Rather than performing a double-lung transplant, the candidate would receive a single lung transplant, and a few months later would receive a second, contralateral single lung transplant.

Policy 10.1.E *LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old* requires transplant programs to update lung candidates’ LAS variables every 6 months. Upon initial registration, the candidate’s data can be up to 6 months old. Therefore, if a candidate undergoes a staged bilateral lung transplant, the candidate’s variables reported for their *second* registration could still be valid even if they were obtained prior to their *first* registration, as long as those variables are not more than 6 months older than the date of the candidate’s *second* registration. OPTN data reveal that there are instances in which transplant programs are reporting variables that pre-date the first transplant for the candidate’s second registration, even when the first graft is not reported to have failed.

After discussion, the Thoracic Committee determined it may be appropriate to prohibit the entry of LAS data that pre-dates a candidate’s previous lung transplant. However, the Committee was hesitant to recommend any policy changes without considering potential unintended consequences on candidates re-registered due to primary graft dysfunction or failure of the first transplant. The Thoracic Committee will also consult with the Ethics Committee regarding potential ethical implications of this surgical practice.

10. Annual Review of Heart Allocation System

On an annual basis, the Thoracic Committee monitors the heart allocation system to determine whether it is achieving its goals and/or whether it has created any unintended consequences. Since 2006 there has been a substantial growth in the number of adult heart candidates registered on the Waitlist, especially in status 1A. There has been an increase in status 1A justifications particularly in criterion (b) (device complications) and criterion (d) (treated with inotropes). Between 2010 and 2013 there has also been a drastic change in the removal rates for death/too sick for status 1A candidates; the overall removals of death/too sick have not significantly decreased, but the distribution of statuses for the removed have.

In the most recent year, there has been a substantial increase in heart utilization rates, from 41 percent to 47 percent. The number of transplants every year is also increasing,

¹ Hartwig, M.G. “Is a Priori Staging of Bilateral Lung transplants the Optimal Surgical Approach for High-Risk Patients with Interstitial Lung Disease?” *Journal of Heart and Lung Transplantation* 33:4 (2014): S30-31. doi: <http://dx.doi.org/10.1016/j.healun.2014.01.111>

with a particularly noticeable increase between 2012 and 2013. Transplant outcomes are also improving.

11. Annual Review of Lung Allocation System

On an annual basis, the Thoracic Committee monitors the lung allocation system to determine whether it is achieving its goals and/or whether it has created any unintended consequences since its implementation in 2005.

There is now a greater percentage of candidates with a high LAS, with 30 percent of candidates registered with an LAS of 40 or higher. In the highest LAS group (LAS of 50 or higher) 10 percent of candidates have a calculated LAS of 60 or higher. In reviewing deaths per patient years on the Waitlist, lower LAS groups and higher LAS groups (LAS between 50-80) have experienced a decline in mortality rate, but candidates with the highest LAS (80 and higher) have experienced an increased mortality rate.

2013 also saw the largest number of lung transplants performed in a single year. There has been a shift in LAS at transplant, with almost 20 percent of recipients in 2013 registered with an LAS of 70 or higher at transplant. Post-transplant survival in the most recent era (2010-2013) in the first year after transplant shows a fairly consistent increase, but after the first year there appears to be a slight drop in survival rates that the Committee may need to explore in greater detail. The oldest transplant recipients have experienced a decline in post-transplant survival. Stratified by LAS at transplant, recipients with an LAS between 20-30 experience the highest survival rates, and surprisingly recipients with an LAS of 90 or higher experienced a slightly higher survival rate than recipients with an LAS between 70-80 and 80-90.

The Committee also reviewed data regarding the cases submitted to the Lung Review Board (LRB). In 2013, only 8 requests for an estimated test value were submitted. The remaining 143 cases were requests for specific scores. Requests for scores for candidates in diagnosis group B (pulmonary hypertension) comprised the majority of the requests. The Committee will continue to monitor these requests, particularly once the LAS modification (approved in November 2012) is implemented in February 2015.

Upcoming Meetings

- The Thoracic Committee does not have any full committee meetings scheduled
- The Lung Subcommittee meets on the third Thursday of every month at 5 p.m. Eastern
- The Heart Subcommittee meets on the fourth Thursday of every month at 5 p.m. Eastern