

**OPTN/UNOS Thoracic Organ Transplantation Committee**  
**Meeting Summary**  
**October 29, 2015**  
**Chicago, IL**

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

*Discussions of the full committee on October 29, 2015 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. Pediatric Lung Allocation Policy Revision**

The proposal was released for public comment in August 2015. It garnered support from several OPTN Committees and passed unanimously in all 11 regions. The American Society of Transplantation, the International Society of Heart and Lung Transplantation and the American Academy of Pediatrics (AAP) submitted support for the proposal and only the AAP provided additional recommendations.

The Thoracic Organ Transplantation Committee (the Committee) considered and addressed public comment feedback received on the proposal. The Committee declined the AAP recommendations to impose member requirements on centers that will be performing intended ABO incompatible transplantation and placing safety monitoring into place before sanctioning intended ABO incompatible lung transplantation in infants. They felt it would be challenging to set performance standards in the absence of sufficient data and such restrictions might further restrict access to ABO incompatible lung transplants. In terms of the latter suggestion, the Committee felt the UNOS evaluation plan was sufficient in terms of monitoring.

Advised by UNOS staff that the terminology for ABO incompatible policy language should be factually accurate and consistent between pediatric heart and pediatric lung, the Committee discussed potential language options. Ultimately, the Committee felt the term "intended incompatible" was the most congruent with "ABO incompatible." They decided to add "blood group" to the phrase for specificity, thus producing the term "intended blood group incompatible" to be used to refer to ABO incompatible transplants in both pediatric lung and pediatric heart policies.

The Committee voted unanimously (19 approve, 0 oppose, 0 abstentions) to adopt the term "intended blood group incompatible," to use this term in the pediatric heart policy for consistency and to send the pediatric lung allocation policy revision proposal to the Board of Directors in December.

### **2. Modification of the Adult Heart Allocation System**

The Committee received an update on progress-to-date on the Modification of Adult Heart Allocation proposal. The Heart Subcommittee continues to refine proposed tier criteria definitions and anticipates releasing the proposal for public comment in January 2016. It is unlikely the proposal will address sensitized patients due to lack of ample data

to develop a fair policy. However, the Subcommittee is discussing whether to require reporting of additional data in order to account for sensitized heart candidates in the future.

### **3. Changes to Heart-Lung Allocation Policy**

This project is currently on hold. The Heart Subcommittee is delaying its conversations regarding heart-lung allocation policy modifications until after the new adult heart allocation tiers are designed.

### **4. Allocation of Deceased Donor Lungs that have undergone Ex Vivo Lung Perfusion**

The Committee was informed this project was on hold. Previously, it decided not to recommend changes to lung allocation policy despite the introduction of EVLP technology to market, and it continues to support this position. The Committee agreed that there are a lack of data that would inform whether this technology is having an adverse effect on prioritization and allocation of lungs, but there is a perceived problem. In the interim, the Committee continues to wait on the outcome of the Organ Perfusion Membership Standards Working Group and will reevaluate whether any additional policy changes are required as a result of the Working Group's recommendations.

## **Committee Projects Pending Implementation**

### **5. Proposal to Collect Extracorporeal Membrane Oxygenation (ECMO) Data upon Waitlist Removal for Lung Candidates**

The Committee was informed that this project is scheduled to be implemented during the second quarter of 2016.

### **6. Proposal to Collect Ex Vivo Lung Perfusion (EVLP) Data for Transplant Recipients**

The Committee was informed that implementation of this project is to be determined as it is pending Office of Management and Budget (OMB) review and approval.

### **7. Pediatric Heart Policy Modifications**

The Committee was informed that work on this project began in October 2015 and the two-part implementation is anticipated in the first and second quarters of 2016. The first phase of implementation, which is anticipated for February 2016, will include the new Status 1A and 1B criteria. The second phase, which is anticipated for the second quarter of 2016, will encompass the changes to the eligibility criteria for pediatric heart candidates willing to accept intended ABO incompatible offers, the change in allocation priority for candidates willing to accept intended ABO incompatible offers, and the elimination of the ability to register a candidate in utero.

## **Implemented Committee Projects**

### **8. Lung Allocation Score (LAS) Modifications**

The revised LAS was implemented on February 19, 2015. The Committee reviewed the data currently available describing the early impact of the revised policy. In summary, there has been a slow, but fairly steady, decline in the number of active candidates who are waiting for a lung or heart-lung. All diagnosis groups had fewer candidates on 9/30/15 compared to 2/19/15, but the largest decline has been seen in Diagnosis Group A (obstructive lung disease).

The waiting list urgency measure appears to have decreased for Diagnosis Group B candidates (which reflects lower waiting list survival, thus leading to higher LAS scores), and appears to have increased for Diagnosis Group D candidates. The post-transplant survival measure has increased for all Diagnosis Groups, with the largest increase seen in Group B, which is likely associated with the more recent patient cohort upon which the revised LAS is based. Diagnosis Group B candidates have experienced the highest increase in ordering by LAS compared to other candidates. Conversely, Diagnosis Group D candidates have experienced a slight decrease in relative ordering compared to other candidates. Until the August 31, 2015 snapshot, Diagnosis Group D candidates had the highest median ordering value, but as of September 30, 2015, Diagnosis Group B has the highest ordering value of 72%.

Changes between pre- and post-implementation and time trends since LAS implementation have varied considerably across regions. The median “ordering” by region is relatively similar from February 19, 2015 and September 20, 2015. Regions with the largest change are Region 6, which increased from 35% to 53%, and Region 11, which decreased from 62% to 45%. There was wide variation across regions in the medians, ranging from approximately 35% to 70%. The Committee noted this variation, especially in Regions 5 and 9. During its project idea brainstorm session, the Committee suggested examining these differences.

These very early results indicate that the LAS revisions have increased the LAS for candidates in Diagnosis Group B, both in absolute terms and in relation to other diagnoses. Several of the revisions to LAS were intended to better reflect the waiting list urgency and post-transplant survival of Group B candidates, so this result was anticipated. Further follow-up time is needed to assess whether results are maintained, predicted waiting list urgency and post-transplant survival reflect actual results overall and by diagnosis group, waiting list mortality and transplant rates have changed and post-transplant survival has been affected.

The Committee was interested in examining why the waitlist is decreasing and regional variation in median ordering of LAS. It will continue to monitor 1) the impact of the revised LAS on candidates with pulmonary hypertension (PH) to determine if the exception to assign PH candidates an LAS equal to the 90th percentile LAS nationwide should continue; and 2) the number of candidates with an LAS of 50 or higher to determine whether 50 is an appropriate cut point for requiring more frequent updates for certain data points for these more urgent candidates.

## **Other Significant Items**

### **9. SRTR Presentation**

The Scientific Registry of Transplant Recipients presented an overview of its role and support services. Specifically, SRTR described program-specific reports and thoracic simulated allocation models.

### **10. Discussion of Future Thoracic Committee Work**

The new OPTN Strategic Plan approved by the Board of Directors in June 2015 included benchmarks for resource allocations towards each of the five strategic goals. This was based on feedback from the community and resulted in an emphasis on increasing the number of transplants and increasing equity in transplant access. The Committee participated in a brainstorming session to identify project ideas that have the potential to

increase the number of transplants. The Committee identified a list of potential projects that included the following:

- DCD lungs
- DCD hearts
- Heart-lung allocation programming project
- Adult adolescent classification exception
- Facilitated thoracic organ placement model
- Donor management of thoracic organs
- Utilization of organs from non-standard donors
- Variance/Alternative listing strategy for centers listing high risk candidates and/or accepting organs from high risk donors
- Factors limiting thoracic program growth
- Standardization of DCD policies (partner with OPO)
- Hep C+ donors
- Payer/transplant center misalignment/payer tolerance of risk
- Decision tools for evaluating offers
- Understand the regional differences in LAS
- SES factors and transplantation/equity and transparency

The Committee will work to further define the projects, draft problem statements, identify proposed solutions, and prioritize these projects.

#### **11. Patient communications regarding lung allocation**

The Committee heard concerns regarding adult lung allocation policy brought forth by a group of concerned patients from Region 6. Two organ procurement organizations (OPOs) service Region 6, but the sole lung transplant program is local to only one of them. Single and double lungs from deceased donors at least 18 years old are allocated to the OPO's local designated service area first, then in 500 nautical mile concentric circles from the donor hospital. Thus, the other OPO begins allocating lungs at classification 7, or Zone A, which includes all transplant hospitals within 500 nautical miles of the donor hospital but outside of the donor hospital's designated service area (DSA). The patient group asked why this OPO would not first allocate lungs to the only lung transplant program in the region, despite it not being in their local DSA.

The Committee tasked the Lung Subcommittee (hereafter, the Subcommittee) with responding to the group. The Subcommittee responded through UNOS Patient Services, indicating that lungs are allocated based on several criteria, not just geography.

Between January 1, 2014 and December 31, 2014, 19 lungs were procured by the Pacific Northwest Transplant Bank. Of these, 11 were accepted at the University of Washington, 2 accepted at the Children's Hospital at Stanford, 4 accepted at Stanford in Palo Alto, CA, and 2 accepted at the University of California San Francisco.<sup>1</sup> When the two organs donated to children (most likely not suitable for adult transplantation due to size) were eliminated, the majority of lung offers were accepted and transplanted at the Region 6 transplant center.

Therefore, the Lung Subcommittee informed the candidates it felt that that they received appropriate priority within the existing system. However, it is the Subcommittee's intent

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<sup>1</sup> Scientific Registry for Transplant Recipients.

to examine broader sharing of adult donor lungs to see whether policy can be further improved.

## **12. Pediatric Bylaws post-public comment modifications**

The Pediatric Committee presented post-public comment modifications to its Pediatric Bylaws proposal. There were several themes pertinent to the thoracic community that were addressed. First, many in the thoracic community felt that the proposed requirements were not appropriate for pediatric lung transplant. In response to public comment feedback, the Pediatrics Committee decided to remove the pediatric lung component requirements due to the small volume of lung transplants, greater geographic disadvantage when compared to other organs, and lack of consensus. The Committee supported this change to the proposal.

Second, the Pediatric Committee reexamined the impact of the proposed requirements on geographic access to transplant for adolescent heart patients. Based on the small number of patients affected, it did not find evidence to support that the proposed requirements negatively impact adolescent access to heart transplantation and did not modify the heart requirements post-public comment.

Third, the most prevalent public comment from both cycles was that the Pediatric Committee needed to include an emergency exception for programs without pediatric components. Based on broad support for such an exception, and in the interest of allowing doctors to execute medical judgment in life-threatening emergencies, the Pediatric Committee modified the proposal to include an emergency pediatric membership exception. One Committee member questioned the emergency exception for heart candidates: if the pediatric community feels that children are better off being treated at a pediatric center, why the exception? He expressed concern over having an exception in place rather than consistent policy. The Pediatric Committee Chair indicated that the exception was added in response to regional feedback.

Finally, the Pediatric Committee rejected a tiered system with different program components for children and adolescents. It felt that excluding adolescents altogether from the Bylaws is inconsistent with NOTA, which specifically defines children, who have unique needs, as less than 18 years old. The Pediatric Committee feels excluding adolescents would not serve the special needs of adolescents compared to adults and runs the risk of permanently defining pediatrics for transplantation as just pre-adolescent children. The Committee deliberated the modifications. Ultimately, some members of the Committee felt there was a lack of compelling data to indicate there was an inherent problem that required a fix, and this proposed solution might introduce unintended adverse consequences.

### **Upcoming Meeting(s)**

- December 10, 2015