

**OPTN/UNOS Thoracic Organ Transplantation Committee**  
**Meeting Summary**  
**June 11, 2015**  
**Chicago, IL**

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

*Discussions of the full committee on June 11, 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 Allocation Policy Review**

The Thoracic Committee reviewed the recommendation of the Lung Subcommittee to make the following changes to pediatric lung allocation policy:

- 1) Prioritize pediatric candidates (0-11 years old) for all offers from adolescent (12-17 year old) and pediatric donors
- 2) Adopt broader sharing of adolescent donor lungs so that adolescent donor lungs are offered to 0-11 year old pediatric candidates in the local DSA, Zone A, and Zone B
- 3) Permit blood type alternative matching for very young lung candidates (registered before two years of age), mirrored after ABO incompatible heart policy

The Committee agreed to adopt the term "alternative blood type match" instead of "incompatible" because for very young candidates, the transplant is not "incompatible." Qualifying candidates are eligible to receive a lung from a donor of a different blood type, because the candidate does not yet make isohemagglutinins at a titer that would cause a donor incompatibility. The Committee also intends to update the pediatric heart policy to also use the term "alternative blood type match" instead of "incompatible."

The Committee voted in favor of distributing these policy changes for public comment during the Fall 2015 public comment cycle (16 approve, 0 oppose, 0 abstentions).

### **2. Adult Heart Allocation Revision**

The Committee received an update regarding the status of the project to revise the adult heart allocation policy. The Heart Subcommittee previously requested the SRTR provide modeling to show the potential impact of adopting a 6-tiered system. The Heart Subcommittee was happy with the results of the initial TSAM. During the morning of the in-person meeting, the Heart Subcommittee finalized its request for additional modeling to review the potential impact of various geographical sharing schemes in addition to the new tiers.

There are still outstanding issues for the Heart Subcommittee to discuss. The first is whether and how to prioritize sensitized candidates. During the morning meeting, the Heart Subcommittee concluded that sensitized candidates cannot be prioritized in the new allocation system because there are not enough data to make an informed policy for these candidates. The Heart Subcommittee instead will develop data points to be

collected during the roll-out of the revised adult heart allocation system that will allow the Heart Subcommittee to prioritize sensitized candidates in the future.

The Committee also discussed whether it should work on heart-lung policy while revising the adult heart allocation system. At the bare minimum, the Committee agreed that it needs to modify Policy 6.5.E: Allocation of Heart-Lungs to replace the reference to Status 1A with an appropriate tier. A small group of the Heart Subcommittee will make additional recommendations to the Heart Subcommittee. The Committee agreed that changes to heart-lung policy should not prevent the rest of the revisions from moving forward to public comment.

### **3. Ex Vivo Lung Perfusion (EVLP) Projects**

The Committee received an update on a number of ex vivo lung perfusion-related projects.

- Data Collection

The Board of Directors passed the EVLP Data Collection proposal during its June 1-2, 2015 Board meeting. The proposal must now go through the Office of Management and Budget (OMB) public comment process, so the implementation date for this project is unknown.

In the meantime, on March 31, 2015, new Tiedi forms went live, including the new Deceased Donor Registration form (DDR). The new DDR contains questions asking about left and right “lung machine perfusion intended or performed?” UNOS Staff presented data collected as a result of these changes. UNOS Staff also explained that OPOs must report the disposition of all organs, including whether the organs were transplanted and, if not, the reason why they were not transplanted. There may be situations where perfusion was performed, but the OPO was not aware of it. The OPTN will only be notified of these transplants when the EVLP-related fields are included on the TRR.

- Membership Work Group

A Work Group was formed under the Member Quality Department to address whether third party perfusion centers should be required to be members of the OPTN. Members of the Work Group believe the OPTN should exercise oversight over these third party perfusion centers, either by requiring the centers to join the OPTN, or by developing a chain of custody process that an OPTN member must follow. The Work Group believes that oversight of the third party perfusion centers would enhance patient safety.

UNOS staff raised some concerns about implementing the Work Group’s suggestions, particularly surrounding requiring OPTN membership, including:

- Does the OPTN have the resources to do so?
- Does it make sense to spend resources on the emerging technology (the perfusion center) whose future is not yet clear?
- Does the OPTN have the expertise to draft membership requirements and monitor compliance with the requirements?
- How would the chain of custody be implemented practically?

UNOS staff provided an alternative solution to the Work Group, suggesting that the Work Group draft a policy change to require OPTN members to include certain terms in the contract they sign with the third party perfusion center, such as that the perfusion center will comply with all the policies that would otherwise be applicable to the OPTN member.

HRSA explained to the Committee that it is currently clarifying the legal authority the OPTN would have to require membership, or enforce compliance with OPTN policies and bylaws for any member other than an OPO or transplant center.

The Thoracic Committee discussed the progress thus far and agrees with the Work Group that OPTN oversight is important, particularly because it does not appear that any other federal entity has complete control over these third party perfusion centers. The Thoracic Committee was not supportive of the proposal to include required terms in a contract, because the transplant center would still ultimately be responsible for the treatment of the organs even though another entity would have physical control for a while. One Committee member suggested that the Work Group move forward with creating membership requirements, but keeping the requirements easy-to-meet, such as requiring participation in an FDA-approved trial, until more data are collected or the field develops further.

- Allocation

The Committee previously determined that allocation policy should not be changed despite the emergence of EVLP. HRSA asked the Committee whether this decision should be re-addressed in the context of lungs that are accepted, perfused by a perfusion center, but ultimately not able to be transplanted into the person for whom the lungs were originally accepted. The Committee reaffirmed its decision to refrain from making any variance proposals or policy changes at this time, because there is not enough volume or experience to be making such significant changes to the allocation scheme. Additionally, the Committee expressed concern that changing policy or creating a variance to permit perfused lungs to be offered only to members participating in a trial sponsored by a third party perfusion center would potentially create an environment in which all centers feel compelled to participate in the trials or risk not receiving any offers at all.

## **New Project Ideas**

### **4. Restructuring the Regional Review Boards (RRBs)**

The Committee identified problems with the current RRB structure. It expressed concern about whether there is impartiality in the review process, whether the current RRB structure is capable of objectivity in the face of rival programs, and whether there is regional decision variability leading to inequitable access.

The Committee brainstormed a number of potential solutions:

- RRBs stay intact, but review cases from outside of their region
- RRBs stay intact, but are staffed by people outside of their region
- RRBs stay intact, but review cases randomly
- Super-Regional Review Board that reviews cases from two or three regions
- National Review Board
- National Pediatric Review Board

The Committee also noted that there is not enough training for RRB members, which may lead them to make decisions that are too prescriptive. The Committee suggested that better communication amongst the RRB members may also resolve some of these issues.

The Committee will explore changing the review board guidelines by the December 2015 Board meeting to reflect some of the solutions mentioned above.

## **5. VAD Requirements for Primary Surgeon Bylaws**

The Membership & Professional Standards Committee (MPSC) previously discussed whether the primary heart transplant surgeon Bylaws should be amended to include training and experience with ventricular assist devices (VADs). The MPSC was supportive of the proposal, and requested the Thoracic Committee's input.

The Thoracic Committee does not agree that the primary surgeon Bylaws should be amended. The Committee agreed that VAD training and competency should be left to individual hospitals to enforce, and that the OPTN should rely on the stewardship of the professionals to refrain from performing surgeries in cases in which they are not trained. The Committee mentioned that there are other types of complicated heart transplant cases that are not governed by the Bylaws, so it did not see why VADs should be treated differently. Additionally, the Committee felt changing the primary surgeon Bylaws would have little to no effect, as there would be no requirement in the secondary surgeon Bylaws to have VAD experience. The Committee suggested the OPTN instead focus on helping to improve and refine the ACGME fellowship requirements. Overall, the Committee did not feel that changing the primary surgeon Bylaws to include VAD training and experience would positively impact patient safety.

## **Implemented Committee Projects**

### **6. Revised Lung Allocation Score (LAS) “Early Results” Data**

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, 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, but Diagnosis Group D candidates still have the highest LAS values as compared to all other Diagnosis Groups.

The early data indicate that the revised LAS is achieving its intended effect thus far, particularly with respect to Diagnosis Group B candidates. The Committee's primary concern based on the data thus far is the significant impact of missing and expired data on candidates' scores. The Committee requested that the lung transplant community continue to be educated on the importance of updating candidates' LAS variables in a timely manner, and may reconsider the default values assigned for missing and expired data if the results continue to be significant. The Committee will also 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 90<sup>th</sup> 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.

As a result of the revised LAS implementation, a small number of candidates had approved score exceptions that were lower than their calculated LAS. UNOS staff notified the transplant programs caring for the candidates to ensure they withdraw the exception so the candidate can receive offers based on the higher, calculated LAS.

However, in order to prevent this problem in the future, UNOS staff asked the Committee whether the system should be programmed to be able to make offers to the higher of the calculated score vs. the exception score in the future, so that intervention by UNOS staff would not be necessary. The Committee voted to submit this request to IT (16 approve, 0 oppose, 0 abstentions).

## **Other Significant Items**

### **7. 2015-2018 OPTN/UNOS Strategic Plan**

The Committee received an update on the newly approved 2015-2018 OPTN/UNOS Strategic Plan. UNOS staff explained the rationale behind the new Strategic Plan, and in the impact it might have on current and future Thoracic Committee projects.

### **8. New Risk Adjustment Models for Post-Heart Transplant Outcomes Assessments**

The SRTR provided a preview of the revised heart risk adjustment models that will be incorporated into the program specific reports (PSRs) for transplant programs. The revisions will be used beginning in the Fall of 2015.

The models are rebuilt every three years, and during each rebuild the SRTR seeks feedback from the Thoracic Committee regarding whether old variables should be retained or whether new variables should be added. Additionally, every six months, parameter estimates are updated to reflect the cohort. Model reports provide first year models and third year models, and provide details on the covariates, the data sources for each covariate, the level of definition for each covariate, the parameter estimates and the graphs of the adjusted effect of each covariate. The SRTR also explained that missing or unknown data will be considered “low risk” by the new risk adjustment models to incentivize data entry.

The Committee discussed the way these PSRs are used. The Committee expressed concern that public posting of PSRs to facilitate transplant center comparison is more concerning, as the public may not investigate the details and draw appropriate conclusions. Additionally, the Committee and SRTR remarked that the PSRs are only as good as the available data; so low volume programs, particularly pediatric programs, may have insufficient data to develop an accurate risk adjustment model. The Committee agreed that use by the Membership & Professional Standards Committee (MPSC) is reasonable, because the MPSC uses these data to flag centers and obtain more details about the centers’ performance.

The revised lung risk adjustment models will be available for preview in the Fall of 2015.

### **9. Memo from the OPO Committee re: FloTrac Monitors**

The Committee received the following memo from the OPO Committee:

The OPO Committee has recently discussed the use of hemodynamic monitoring devices such as FloTrac in place of pulmonary artery catheters. While FloTrac type devices measure many of the same measures, it appears that in patients who are hemodynamically unstable or are being volume resuscitated, there isn't concordance between PAC and FloTrac type monitors.

The OPO Committee is supportive of pursuing an OMB change to the deceased donor registration form (DDR) to allow for these measures to be entered for a FloTrac type of monitor. The OPO Committee also

discussed how this information is entered in DonorNet® and communicated to the transplant hospitals.

The OPO Committee is requesting your input on the importance of making these changes. If you have any questions, please don't hesitate to contact me.

The Thoracic Committee shared its experience with the use of FloTrac monitors. It agreed that FloTrac monitors provide hemodynamic measures for a very specific type of patient, but otherwise often provide measures that are discordant with the measures obtained through more traditional methods. The Committee agrees that DonorNet and the DDR form should be changed to reflect how the reported hemodynamic measures were obtained to allow the Committees to differentiate the measures.

#### **10. Question from a Member Regarding Hemolung**

A member asked UNOS staff how Hemolung would affect a candidate's lung allocation score (LAS). The member was advised that it should follow the same advice the Thoracic Committee previously published for candidates on ECMO: enter the candidates' lab values into the LAS calculator, and report "continuous mechanical ventilation" and an FiO<sub>2</sub> of 100%. After obtaining the candidate's calculated score with those variables, the member should request a score exception from the Lung Review Board. The Thoracic Committee discussed Hemolung and determined it is very similar to veno-venous ECMO, and therefore the advice UNOS staff provided was sound.

#### **Upcoming Meeting**

- October 29, 2015