Thoracic Organ Transplantation Committee Meeting Summary March 24, 2016 Chicago, IL

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Discussions of the full committee on March 24, 2016 are summarized below. All committee meeting summaries are available at <u>http://optn.transplant.hrsa.gov/</u>.

Committee Projects

1. Modification of the Adult Heart Allocation System

The Thoracic Organ Transplantation Committee (hereafter, referred to as the Committee) reviewed public comment feedback. General critiques and potential solutions were presented for the proposed statuses and broader sharing. The Committee reached consensus that the proposal will require another round of public comment. UNOS staff asked the Committee to consider what changes they would make, and what evidence could support those changes (i.e. is further modeling required). The Committee will determine whether it is feasible to release a modified proposal during the August 2016 or January 2017 public comment cycle.

2. Allocation of Deceased Donor Lungs that have undergone Ex Vivo Lung Perfusion

This project remains on hold but was discussed at the Lung Subcommittee breakout. Previously, it was decided not to recommend changes to lung allocation policy despite the introduction of EVLP technology to market, and the Committee continues to support this position. The Committee agreed that there is 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.

3. Changes to Heart-Lung Allocation Policy

This project is currently on hold. The Heart Subcommittee will continue to delay conversations regarding heart-lung allocation policy modifications until after the adult heart allocation system proposal is sent to the Board of Directors. This project may get rolled up into a multi-organ initiative.

Committee Projects Pending Implementation

4. 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 April 14, 2016.

5. 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.

6. Pediatric Heart Policy Modifications

The Committee was informed Phase 1 of this project was implemented March 22, 2016. Phase 2 is pending Office of Management and Budget (OMB) approval.

7. Pediatric Lung Allocation Policy Revision

The Committee was informed IT work is scheduled to begin the end of the 4th quarter 2016.

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, the waiting list urgency measure decreased in diagnosis group B (shorter life on the wait list) and increased in diagnosis group D (longer life on the wait list). All groups experienced a small increase in the post-transplant survival measure (i.e. longer expected post-transplant life). Median "ordering" increased substantially for diagnosis group B and decreased for diagnosis group D. There has been a decrease in the number of Lung Review Board (LRB) requests and a decline in the difference between the calculated LAS and the exception LAS requested. Finally, waiting list mortality appeared to decrease overall and for all diagnostic groups except group C, but comparisons were not statistically significant.

These very early results indicate that the revisions have led to an increase in the LAS for group B candidates, both in absolute terms and in relation to other diagnoses. This change was anticipated. Further follow-up is required to assess if these changes are persistent, if predicted waiting list urgency and post-transplant survival accurately reflect outcomes, and if waiting list mortality and transplant rates have changed.

The Committee identified several areas that warranted further investigation, including:

- Relative LAS ordering, transplantation and mortality rates by region and by diagnosis within region;
- The increase in wait list mortality rates for candidates with a LAS of 60-<70 and for those in diagnosis group C
- The relatively high rate of LRB refusals compared to other groups for score requests in diagnostic group A
- Geographic variability of median "ordering" by region
- Comparison of LAS and individual factors in LAS calculation (e.g., oxygen use at rest) for patients who are multiply listed

UNOS staff will solicit clarification on some of the LAS data points presented to codify into a formal data request. In addition, by the fall 2016 committee meeting, UNOS staff will provide post-transplant survival for transplants performed after LAS revision.

Review of Public Comment Proposals

9. KAS Clarifications

The Committee supported informed consent for multi-organ candidates. The Committee felt that it would be appropriate to inform the patient before transplant when clinicians can better inform the patient of the risks. In addition, heart candidates (who need a

kidney) are able to be stabilized in a manner that would allow for time to obtain informed consent when the patient is able to make that determination.

10. National Liver Review Board

This proposal was presented to the Committee for informative purposes only as the Heart Subcommittee considers whether to pursue proposing a National Heart Review Board, as is being proposed for Liver and is already in place for Lung.

Other Significant Items

11. Policy Oversight Committee Update

The Vice Chair debriefed on the Policy Oversight Committee meeting. Specifically, the Vice Chair emphasized the need for Goal 1 and Goal 3 projects to balance the OPTN project portfolio. Goal 2 is currently over-allocated.

12. Lung Subcommittee Breakout

The Committee discussed several Goal 1 and Goal 3 project ideas:

- Increase procurement and transplantation of DCD Lungs
- Facilitated thoracic organ placement model
- Alternative ventilator management strategies to increase the pool of viable donor lungs/Donor management of thoracic organs
- Factors limiting thoracic program growth/removing disincentives
- Allocation of Deceased Donor Lungs that Have Undergone Ex Vivo Lung Perfusion (EVLP)

The Committee prioritized the first two project ideas to discuss further.

13. Scientific Registry of Transplant Recipients (SRTR) Update

The SRTR provided an update on the Thoracic Simulated Allocation Model (TSAM). Updates to the TSAM include more contemporary cohorts and updated statistical models. SRTR estimates the new TSAM will be released July 2016.

14. Committee Engagement Survey

UNOS staff led a discussion on how liaisons can communicate more effectively with the Committee. The goal of this discussion was to generate feedback that the policy department can use to improve our overall communications. Staff developed a survey for Committee members to complete seeking feedback in the following areas:

- Volume of communication
- Type of communication
- Effectiveness of communication
- Value or the content being communicated

Upcoming Meeting

• April, 2016