

**OPTN/UNOS Thoracic Organ Transplantation Committee
Meeting Minutes
March 23, 2017
Richmond, VA**

**Kevin Chan, MD, Chair
Ryan Davies, MD, Vice Chair**

Introduction

The Thoracic Organ Transplantation Committee (Committee) met via Citrix GoToTraining teleconference and in-person in Richmond, VA to discuss the following agenda items:

1. Public Comment and Pre-Public Comment Proposal Review
2. Thoracic Committee Project Portfolio Review and New Project Prioritization
3. Other Committee Business

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

1. Public Comment and Pre-Public Comment Proposal Review

The Committee reviewed the Liver & Intestine Committee *National Liver Review Board* proposal and provided pre-public comment feedback to the Pediatric Committee's *Pediatric Emergency Membership Exception Pathway for Heart*.

Summary of discussion:

National Liver Review Board – Liver and Intestine Committee

The Committee reviewed this proposal primarily for informational purposes, as the Heart Subcommittee is considering nationalizing the review board system for heart, as is proposed for liver and is already in place for lung. Members posed the following questions, which were answered to the satisfaction of the Committee:

Q: How large is the pool of individuals who would serve on the national review board?

A: Every liver transplant program may appoint a representative to a pool of review board members. Members could serve on multiple boards.

Q: How many pediatric liver programs are there?

A: The number of pediatric liver programs are slightly less than half of the number of adult liver programs. A separate pediatric review board is proposed since currently adult hepatologists occasionally have to review pediatric liver exception cases, similar to what occurs within the heart regional review boards.

Q: What is the financial impact of this proposal?

A: This proposal will require programming in UNet, estimated to be an "Enterprise" level project. However, this programming will eliminate several manual processes for UNOS Review Board staff, which will result in long-term cost-savings. Review Board staff will still be responsible for facilitating conference calls for programs that choose to appeal a case to the NLRB after a second randomized review results in a denial. UNOS does not anticipate having to add staff to support the implementation of this proposal.

Q: Operationally, how will review board members vote and provide feedback?

A: The Liver review board system is currently operationalized through UNet, unlike heart, which is a manual process. The proposal calls for automating approval of exception

requests that meet specific parameters. The current timeframe of 7 days to submit a vote is not being changed.

Q: How did the Liver Committee determine what the majority should be to approve a request? Is the five member review panel randomly selected on monthly basis?

A: The Liver Committee opted for a five member review panel and modeled the decision for a super majority (4/5) based on the Membership and Professional Standards Committee (MPSC) peer review process. Five individuals are randomly assigned to each case. The Appeals Review Team (ART) is assigned on a monthly schedule: All NLRB members are assigned to serve one month each year on the ART (9 member teams, require 5 for quorum).

Q: Could this restructure result in an increased workload for individuals from regions with few liver programs, versus individuals from regions with many liver programs?

A: Yes, it is possible that physicians currently in regions with few liver programs that did not see many exceptions or appeals come through may see an increased workload now that cases will be redistributed nationally. UNET programming efficiencies should mitigate the workload.

Q: Does the Liver Committee think that the standardization and uniformity in evaluating exception requests will be gained through the formal education and guidance provided in the guidance documents, rather than how the national review board will be operationalized?

A: Yes. The guidance is an integral part of this proposal and is what the Liver Committee hopes will help achieve more consistency in evaluating exceptions, in addition to the creation of a standard template for data and information collection.

Q: Did the Liver Committee consider shortening the timeframe to evaluate exceptions? In the heart community, many exception 1A requests are time-sensitive due to high severity of illness.

A: There is a different system for critically ill liver candidates requesting elevation in status to status 1. This process is not affected by this proposal. These cases are retrospectively reviewed by a subcommittee of the Liver Committee. Inappropriate listing via this pathway may result in center referral to the MPSC. Liver programs can also request a prospective review for urgent cases, which prompts an expedited review by the subcommittee.

A Committee member pointed out the structure of the national Lung Review Board (LRB) is different than that proposed by the Liver Committee. If the Thoracic Committee pursues a national review board for heart, it may be beneficial to standardize protocols and resources for all national review boards. Members liked the template to standardize data and information the review board deems critical to making a decision.

Pediatric Emergency Membership Exception Pathway for Heart – Pediatric Committee

The Pediatrics Committee presented their proposal on the emergency heart pediatric membership exception pathway criteria for pre-public comment feedback. Members posed the following questions, which were answered to the satisfaction of the Committee:

Q: Is the requirement that the candidate is either on a surgically implanted, non-endovascular ventricular assist device (VAD) not FDA-approved for use outside the hospital or extracorporeal membrane oxygenation (ECMO) *and* transport is not medically advisable?

A: Yes. The candidate would have to meet one of those criteria and the adult transplant program would have to contact a pediatric program and advise the candidate is not transportable, and therefore should remain (to be transplanted) at the adult center.

Q: Is the requirement for surgically implanted, non-endovascular VAD not FDA-approved for use *in children* outside the hospital, or just generally not approved for use outside the hospital?

A: Not FDA-approved at all for use outside the hospital.

Q: Did the Pediatric Committee consider how parental preference would affect compliance with the new bylaw requirement generally? i.e. if a parent did not want their child transferred to a pediatric program because they developed a relationship with the adult providers. Several members echoed this concern.

A: Once the bylaws go into effect, only approved pediatric programs will be able to list and transplant pediatric patients, unless the case meets the emergency exception criteria. This was discussed at length during the ten year development of the pediatrics bylaws proposal.

Q: Are these Bylaws already approved by the Board? If so, when is anticipated implementation?

A: Yes, these Bylaws were approved by the Board in December 2015 with amendments to develop emergency exception criteria for liver and heart. These Bylaws will not be fully implemented until the emergency exception pathways are approved by the Board of Directors. The Pediatric Committee anticipates this will go out for public comment in the fall of 2017.

2. Thoracic Committee Project Portfolio Review and New Project Prioritization

Data summary:

UNOS staff presented data from the following requests during the Committee's project portfolio review discussion.

Lung Allocation Score (LAS) Revision - Monitoring Report

On February 19, 2015 the LAS modifications were implemented. Changes in LAS scores by diagnostic group were requested. Committee discussion is detailed below.

Data Collection for Highly Sensitized Lung Candidates

The Lung Subcommittee is contemplating pursuing a project to collect data on highly sensitized candidates. To analyze the problem, they requested tabulations of the number of lung matches for which a candidate with any reported unacceptable antigens (UAs) would be screened off due to UAs, regardless of other criteria. Committee discussion is detailed below.

Allocation to Account for Candidate Stature

In response to recent publications and member inquiries suggesting that candidates of short stature are disadvantaged by the current lung allocation system, the Lung Subcommittee requested waiting list mortality rates and transplant rates stratified by candidate height. Candidate heights were condensed into three broad categories for the analysis: under 5 feet, between 5 and 6 feet, and over 6 feet. Waitlist mortality was consistent across all height groupings with roughly 8 deaths per 100 patient years. Transplant rates were more variable. Candidates under five feet tall were transplanted at a lower rate than taller candidates, with 70 transplants per 100 patient years. Candidates between 5 and six feet tall saw 176 transplants per 100 patient years, while candidates over six feet tall received 308 transplants per patient year waited. There was no substantive discussion regarding this data.

National heart review board

The Heart Subcommittee has discussed the possibility of converting the regional review board system to a national system. To analyze the problem, the Heart Subcommittee requested data on exception requests by region, including pediatric exceptions. Conveniently, this information was provided to each region during the spring 2017 meeting cycle. Acknowledging that the new

adult heart allocation policy will include many clinical scenarios that are not included in current policy, the Subcommittee looked at the exception volume as a metric that may provide an estimate of national review board workload. As the Liver Committee acknowledged, some members of a national review board would review a greater number of cases than they might on the regional level.

Summary of discussion:

Lung Subcommittee

- Project Portfolio

The Subcommittee shared updates on active projects in their portfolio. Two projects were recently approved by the Policy Oversight and Executive Committees. The Subcommittee prioritized working on the Modification of the Lung Transplant Follow-up Form (TRF) to include CLAD Data and recently requested data to examine how transplant centers currently use the Bronchiolitis Obliterans Syndrome (BOS) field on the OPTN Transplant Recipient Follow-Up Forms (TRF) to help understand the current state of reporting. They will transition to the Lung Allocation Score (LAS) Refinements and Clean-up project over the summer and anticipate both projects will go out for public comment in the spring of 2018.

Two lung projects have been approved by the Board of Directors and are pending implementation. The changes to pediatric lung policy will be implemented on March 30th, 2017. The ex vivo lung perfusion (EVLP) Data Collection project is pending The Office of Management and Budget (OMB) approval. The Subcommittee received an update on the Lung Adolescent Classification Exception in the fall of 2016 and will receive future updates upon request moving forward. The Subcommittee continues to monitor ECMO data collection changes and revisions to the LAS.

As part of regular monitoring, the Committee reviewed LAS by diagnostic group as well as transplant rates and wait list mortality based on candidate height. LAS values at listing were found to be significantly higher for diagnostic group B and significantly lower for diagnostic group D after LAS revision. Despite the increase in group B ordering, the lung review board continues to receive exception requests for this group, although the number of requests has decreased. The need to continue the group B exception guidance recommendation will be examined as part of the LAS Refinements and Clean-up project. Another member asked about how the lung review board looks at exceptions-is there a way to look at the data more real-time, or further stratify a broad group of patients, such as the pulmonary hypertension patients, into more homogeneous cohorts to aid in decision-making? UNOS staff advised there are more real-time data analysis options the Committee could explore.

The Subcommittee reviewed information data pertaining to highly sensitized lung candidates. In 2016, 915 adult candidates were listed with unacceptable antigens (UAs) while 2296 lung organ donors were procured. Highly sensitized candidates had few to no potential donors. Across candidate ABO, AB candidates saw the most potential donors, followed by A candidates. O candidates had the fewest. Highly sensitized candidates across all blood groups waited longer to receive a lung transplant. Based on this preliminary data, the group debated the need to further evaluate and develop a policy to increase access to potential organs for this group within the LAS system. They acknowledged that few programs are entering UAs, so data analysis is not accurate, therefore a policy solution is not possible at this time. Because reporting UAs is a barrier to receiving lung offers, mandated reporting of CPRA and other data may not be popular with the community. One member asked whether the Subcommittee could look at refusal data, and the number of offers turned down due to UAs. Another member suggested looking at the patient population

listed at centers who report UAs to determine waitlist mortality and post-transplant survival in this group. Potential solutions mentioned were prioritizing candidates above the rest for a short window of time or incentivizing transplantation of highly sensitized patients by adjusting outcome metrics to reduced risk-avoidance behaviors. The Subcommittee prioritized this project idea but tabled further discussion until a future Subcommittee meeting.

- New project prioritization:
 - The Subcommittee chose to prioritize the following projects over the coming months:
 - Data Collection for sensitized lung candidates
 - Analyzing geographic differences in LAS
 - Increasing Utilization of DCD Donor Lungs
- Member Inquiry
 - The Subcommittee briefed the full Committee on an inquiry by the Cystic Fibrosis Foundation requesting a review of waitlist mortality and transplant rates in CF patients.

Heart Subcommittee

- Project Portfolio
 - **Modification of the Adult Heart Allocation System**
 - UNOS staff provided an update regarding heart allocation policy implementation efforts. The Committee advised considering an in-person to improve efficiency
 - **Congenital Heart Disease Guidance Document**
 - The Committee felt that the proposed guidance was too general. If the goal of developing guidance for the regional review boards is an attempt to increase consistency in evaluating those exception requests, the guidance should be more specific. The Vice Chair explained that simplified guidance will allow the review boards to assess cases without being overly prescriptive. In addition, there is variation in waitlist mortality risk and a lack of data that would support escalating these candidates to a higher status, which was a challenge the Committee faced during the development of the heart allocation proposal. Rather, the Committee's decisions were informed by clinical consensus. The workgroup will consider the Committee's feedback.
 - **Hypertrophic Cardiomyopathy/Restrictive Cardiomyopathy Guidance Document**

This guidance document will be developed in collaboration with external experts. The first meeting is scheduled for April 28, 2017. One Committee member recommended that this document go out for public comment and to the Board in tandem with the CHD guidance document. Another member reminded the Committee that there were more specific criteria in the approved policy for amyloidosis, hypertrophic or restrictive cardiomyopathy candidates, as opposed to the CHD policy.
- New project prioritization
 - The Subcommittee chose to prioritize the following projects over the coming months; there was consensus that these could potentially all be incorporated into one project:
 - National Heart Review Board
 - National Pediatric Heart Review Board
 - Developing a formal orientation for Heart Review Boards

Next steps:

- The Subcommittees will continue to work on active projects.
- UNOS staff will look into the feasibility of an in-person heart allocation implementation meeting.

3. Other Significant Items

Policy Oversight Committee Update

The Vice Chair provided an update on strategic alignment of the OPTN project portfolio and recently approved projects.

Board of Directors Recruitment

UNOS staff presented operational changes and open positions on the 2018-2019 Board of Directors roster. Staff reviewed the process of nomination and self-nomination to a board position.

Scientific Registry of Transplant Recipients (SRTR) Presentation

The Committee requested SRTR present the analysis and motivation behind the new tier rating system. While the Committee agrees with the goal of the changes: especially providing more relevant and transparent information to potential candidates, there were important concerns with the methodology being used. In particular, the Committee inquired whether SRTR felt that there were significant and important differences between centers in adjacent tiers, such that SRTR felt that a patient making a choice based on outcomes should choose one over the other, when survival rates might be within a percentage point of each other. SRTR did not comment on whether they felt that was a meaningful distinction. There was also concern regarding the underlying models used to estimate the expected survival. In particular, the models have only moderate correlation with outcomes and ignore multiple clearly relevant factors (socioeconomic status, pre-transplant physical conditioning, detailed congenital diagnosis, and the number of prior sternotomies). The SRTR argued that the models were as good as could be derived from the collected data and that—in aggregate—the overall survival in 5-star programs was significantly different from that in 4-star programs, but the Committee again pointed out that this had no bearing on the likelihood that there were real differences between two individual programs in different tiers. There was also concern that this information will be used by insurance companies to steer patients to different centers. In addition, when programs are faced with a patient perceived to be “high-risk” based on factors not included in the models, it will catalyze those programs to become more conservative in behavior, which in turn will affect access and transplant numbers. The SRTR did not express an opinion regarding the consequences of the changes in regards to program decision-making. While the SRTR pointed out that website visitors could choose to look at the data in multiple ways, members of the Committee noted that the website search function defaults to ranking results by outcome assessment, and members felt that makes that indicator the de facto most important information patients will use to compare programs (as opposed to other potentially more valuable numbers including waitlist survival and likelihood of transplantation.). Another suggestion was to include historical performance trends, so patients could see whether a program bounced around between tiers, or has remained in a tier over time. This would also have the advantage of evaluating whether the estimates are stable over time and relevant in predicting outcomes in the coming year. The public comment cycle to collect feedback is currently open, and the SRTR shared that they have a grant to solicit patient feedback regarding the website to help improve it. They will continue to review the data and modify the website.

Systems Optimization Project Update

The OPO Committee is currently working on a project to address inefficiencies in the current allocation system that may cause usable organs to be discarded. The Thoracic Committee representative to this workgroup provided a progress update. The workgroup anticipates sending the proposal out for public comment in the fall of 2017.

Donor Management Metrics Project

A representative from the Donor Management Leadership Council, part of the Organ Donation and Transplantation Alliance (Alliance), presented organ-specific outcome metrics to guide donor research investigators in order to identify the potential for unmonitored adverse events affecting other potential transplantable solid organs during donor research (e.g., a kidney study having unexpected cardiac consequences). The project goal was to obtain feedback from a professional society for each set of organ-specific metrics. The ISHLT Board approved the Thoracic metrics with the proviso that they be forwarded to the UNOS Thoracic Committee for review. The Committee provided the following feedback on this 2011 document:

- Lung metrics:
 - Add renal insufficiency
 - Add EVLP for lungs
 - Add donation after cardiac death (DCD) (yes or no)
 - Add antibody-mediated rejection (AMR)
- Heart metrics:
 - Merge “hemodynamically significant” rejection episode data element with acute cellular rejection (ACR) or AMR question, but no consensus. Others felt question was sufficient as is.

Upcoming Meeting

- June, 2017

Attendance

- **Committee Members**
 - Kevin Chan, MD
 - Ryan Davies, MD
 - Jane Farr, MD
 - Tim Whelan, MD
 - Jonathan D’Cunha, MD
 - Nirav Raval, MD
 - Mark Drazner, MD
 - Mark Barr, MD
 - Erika Lease, MD
 - Rocky Daly, MD
 - Andrew Kao, MD
 - Jules Lin, MD
 - Chad Denlinger, MD
 - Masina Scavuzzo, RN
 - Jeff Goldstein
 - Karen Lord, RN
 - Marc Schecter, MD
 - Melanie Everitt, MD
 - Joseph Rogers, MD
- **HRSA Representatives**
 - Joyce Hager
 - Jim Bowman, MD
- **SRTR Staff**
 - Katie Audette
 - Melissa Skeans
 - Bert Kasiske, MD
 - Noelle Hadley
- **OPTN/UNOS Staff**
 - Kim Uccellini, MS, MPH
 - Liz Robbins Callahan, Esq.
 - Jeff Davis
 - Bob Carrico, PhD
- **Other Attendees**
 - Julie Heimbach, MD
 - David Nelson, MD