

**OPTN/UNOS Thoracic Organ Transplantation Committee  
Report to the Board of Directors  
June 1-2, 2015  
Atlanta, Georgia**

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

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*This report reflects the work of the OPTN/UNOS Thoracic Organ Transplantation Committee during the November 2014 to April 2015 period.*

**Action Items**

1. Proposal to Collect Extracorporeal Membrane Oxygenation (ECMO) Data Upon Waitlist Removal for Lung Candidates

*Public Comment: [September – December 2014](#)*

Extracorporeal membrane oxygenation (ECMO) has become a more common treatment for patients with end-stage lung disease awaiting lung transplantation. The Thoracic Committee has been unable to consider the impact of ECMO support on lung allocation because this information is not routinely collected and reported to the OPTN. The Thoracic Committee proposes the collection of ECMO information at the time of waiting list removal to retrospectively capture each candidate's mechanical oxygenation and ventilatory support history. This will provide the Thoracic Committee with data on a contemporary cohort of candidates in order to appropriately analyze how ECMO should be incorporated into the LAS calculation.

The Committee considered and addressed public comment feedback received on its proposal (**Exhibit A**). After careful review, the Committee voted to recommend the following modification to Waitlist<sup>SM</sup> for consideration by the Board of Directors:

**RESOLVED, that modifications to the Waitlist<sup>SM</sup> application, as set forth in Exhibit A, are hereby approved, effective pending programming.**

2. Proposal to Collect Ex Vivo Lung Perfusion (EVLP) Data for Transplant Recipients

*Public Comment: [January – March 2015](#)*

Ex vivo lung perfusion (EVLP) is an emerging technology that can be used during transport, and to preserve and condition lungs prior to transplantation. The utilization of EVLP is not currently reported to the OPTN, so the OPTN cannot determine how many lungs have been perfused and then transplanted. In the spring of 2015, the OPTN will implement changes to the OPTN Tiedi<sup>®</sup> forms, including the Deceased Donor Registration form (DDR). Through the modified DDR, Organ Procurement Organizations (OPOs) will report whether an accepting transplant program intends to perfuse the lungs prior to transplant. However, there is no corresponding field on the Transplant Recipient Registration form (TRR) for transplant programs to report whether lungs were perfused prior to transplant. The Thoracic Committee believes it is important to capture this information to monitor lung allocation, recipient safety, and organ and patient outcomes. This information will also be important for future policy development and risk adjustment for member-specific performance measures.

The Committee considered and addressed public comment feedback received on its proposal (**Exhibit B**). After careful review, the Committee voted to recommend the following

modifications to the Transplant Recipient Registration form in Tiedi for consideration by the Board of Directors:

**RESOLVED, that modifications to the Transplant Recipient Registration form in the Tiedi® application, as set forth in Exhibit B, are hereby approved, effective pending programming.**

### Committee Projects

#### 3. Pediatric Lung Allocation Policy Revision

*Public Comment: August, 2015 (Estimated)*

*Board Consideration: December, 2015 (Estimated)*

After a comprehensive review of pediatric lung allocation policy, the Lung Subcommittee identified three ways to improve the overall fairness of the system: 1) by implementing broader sharing of child (0-11 year old) and adolescent (12-17 year old) donor lungs; 2) by prioritizing children for offers from adolescent donors; and 3) by permitting ABO-incompatible (ABOi) transplants for very young lung candidates.

For the first two measures, the Lung Subcommittee reviewed results of Thoracic Simulation Allocation Modeling (TSAM) performed by the SRTR. The TSAM modeled the following sequences:

Allocation Sequence Name	Description
Share Child	Prioritizes 0-11 year old candidates for 0-11 year old donor lungs, with broader sharing
Share Adolescent	Prioritizes 12-17 year old candidates for 12-17 year old donor lungs, with broader sharing
Share Both	Prioritizes 0-11 year old candidates for 0-11 year old donor lungs and prioritizes 12-17 year old candidates for 12-17 year old donor lungs, both with broader sharing
Child Priority	Prioritizes 0-11 year old candidates for both 0-11 year old and 12-17 year old donor lungs, with broader sharing

The Subcommittee eliminated “Share Child,” since modeling results were similar to current allocation. It also preferred “Share Both” over “Share Adolescent,” since results were similar. There were no predicted waitlist mortality differences across any of the allocation sequences, for any of the candidate age groups. Similarly, there were no differences detected in one-year post-transplant mortality rates across any of the allocation sequences, for any of the candidate age groups.

The Subcommittee deliberated the benefit of the “Share Both” and “Child Priority” allocation sequences. While adolescent candidates (12-17 year old) experience dramatically increased transplant rates under either, the only modeled allocation sequence that clearly benefits child (6-11 year old) candidates is “Child Priority.” Some members expressed concern that prioritizing child candidates for adolescent donor lungs could disadvantage small adolescents. Others wondered if this additional priority was needed since children have access to the adolescent classification exception. Some preferred automatic priority for child candidates in the allocation system to an exception process, which could be inconsistently applied.

To inform its decision, the Subcommittee reached out to the Pediatric Committee and the Ethics Committee. The Pediatric Committee is supportive of “Child Priority.” In addition to the adolescent classification exception, the Pediatric Committee questioned whether an exception was necessary for very small 12 to 17 year olds, who otherwise may be disenfranchised, to be classified as 6 to 11 year olds. The Pediatric Committee ultimately determined that broader sharing will have such a remarkable benefit for adolescents overall that an exception is not needed, and the small number of child candidates will mean that small adolescents will still receive acceptable offers. The Ethics Committee expressed support generally for broader sharing and pediatric priority and stated that either allocation sequence was ethically defensible. After considering this feedback, the Lung Subcommittee will make a final recommendation to the Thoracic Committee in June.

The Lung Subcommittee also continues to discuss modifying policy to permit ABOi lung transplants for the youngest lung candidates. The Subcommittee’s discussions centered on how closely to model ABOi heart policy. The Subcommittee is still finalizing its recommendation, but is likely to suggest the Thoracic Committee sends out for public comment a proposal that mirrors the eligibility and isohemagglutinin titer reporting requirements in the ABOi heart policy adopted by the Board of Directors in June 2014. The ABOi lung policy and the broader sharing/child prioritization proposal are currently on schedule to be released for public comment in August 2015.

For more information, see the Lung Subcommittee meeting minutes from October 16 and November 20, 2014, and January 15 and February 19, 2015.

4. Modification of the Adult Heart Allocation System

*Public Comment: January, 2016 (Estimated)*

*Board Consideration: June, 2016 (Estimated)*

The Heart Subcommittee developed a “straw man” version of potential new medical criteria tiers for the heart allocation system:

<b>Tier</b>	<b>Proposed Criteria</b>
<b>1</b>	<ul style="list-style-type: none"> <li>i. ECMO</li> <li>ii. Mechanical ventilation</li> <li>iii. Non-dischargeable (surgically implanted) VAD</li> <li>iv. Mechanical circulatory support with life-threatening ventricular arrhythmia</li> </ul>
<b>2</b>	<ul style="list-style-type: none"> <li>i. Intra-aortic balloon pump</li> <li>ii. Ventricular tachycardia/ventricular fibrillation, mechanical support not required</li> <li>iii. Mechanical circulatory support with device malfunction/mechanical failure</li> <li>iv. Total artificial heart</li> <li>v. Dischargeable BiVAD or RVAD</li> <li>vi. Acute circulatory support</li> </ul>
<b>3</b>	<ul style="list-style-type: none"> <li>i. LVAD for up to 30 days</li> <li>ii. Status 1A exception</li> <li>iii. Multiple inotropes or single high-dose inotropes with continuous hemodynamic monitoring</li> <li>iv. Mechanical circulatory support with device infection</li> <li>v. Mechanical circulatory support with thromboembolism</li> <li>vi. Mechanical circulatory support with device-related complications other than infection, thromboembolism, device malfunction/mechanical failure or life-threatening ventricular arrhythmia</li> </ul>

<b>Tier</b>	<b>Proposed Criteria</b>
<b>4</b>	<ul style="list-style-type: none"> <li>i. Diagnosis of congenital heart disease (CHD) with:               <ul style="list-style-type: none"> <li>a. Unrepaired/incompletely repaired complex CHD, usually with cyanosis</li> <li>b. Repaired CHD with two ventricles (e.g., TOF, TOGV)</li> <li>c. Single ventricle repaired with Fontan or modifications</li> </ul> </li> <li>ii. Diagnosis of ischemic heart disease with intractable angina</li> <li>iii. Diagnosis of hypertrophic cardiomyopathy</li> <li>iv. Diagnosis of restrictive cardiomyopathy</li> <li>v. Diagnosis of amyloidosis</li> <li>vi. Stable LVAD candidates after 30 days</li> <li>vii. Inotropes without hemodynamic monitoring</li> <li>viii. Retransplant</li> <li>ix. Status 1B exceptions</li> </ul>
<b>5</b>	Approved combined organ transplants: heart-lung; heart-liver; heart-kidney
<b>6</b>	All remaining active candidates
<b>7</b>	Inactive/not transplantable

The SRTR performed a Thoracic Simulation Allocation Model (TSAM) using these tiers to model the potential impact these tiers may have on heart candidates. The modeling shows that transplant rates for candidates in the most urgent tiers are likely to increase, waiting list mortality rates are predicted to stay similar to current allocation, though the death count is lower than in the current system, and post-transplant mortality rates might increase under the tiered system. The Subcommittee weighed the benefits of giving more urgent candidates quicker access to transplant, and thus reducing the waitlist mortality rates, while also acknowledging a potential uptick in post-transplant death counts. The Subcommittee currently agrees that the tiers, as modeled in the TSAM, are appropriate and should be included without modification in the public comment proposal.

With agreement on the tiers achieved, the Subcommittee will discuss two additional potential modifications to the heart allocation policy: 1) geographic sharing; and 2) sensitized candidates. The Subcommittee is developing various modifications to the current zonal geographic sharing scheme to determine whether adopting a form of broader sharing would further benefit heart candidates. The SRTR will perform additional TSAMs based on these broader sharing scenarios.

The Subcommittee has also held a number of discussions regarding how to define and whether to prioritize sensitized candidates in the new allocation scheme. A significant challenge with the data collected by the OPTN/UNOS is that unacceptable antigens (UAs) are not currently required to be reported for heart candidates, so there is likely underreporting of UAs. Due to the complications posed by the current data, Subcommittee members questioned whether the focus should instead be on collecting more data by incentivizing programs to report UAs, rather than on implementing a solution for sensitized candidates within the revised policy. Subcommittee members agreed that collecting more data is critical, particularly as treatment of candidates with heart failure tends to move towards device-support and the need for more operations (increasing the likelihood of introducing the candidate to sensitizing events). However, the Subcommittee has not reached consensus regarding whether they should also attempt to provide some advantage for some sensitized candidates.

The Subcommittee debated whether to release the tiers for public comment in August, 2015, while continuing to develop the geographic sharing and sensitization aspects of the policy

for January 2016 public comment. The Subcommittee ultimately decided that the proposal should be released at once to avoid creating confusion within the community. In the meantime, Subcommittee members are presenting the status of their progress to forums at the International Society for Heart & Lung Transplantation and the American Transplant Congress. Members of the Subcommittee have also published articles informing the community of the rationale and status of the proposed changes. The Subcommittee anticipates releasing the proposal for public comment in January 2016.

For more information, see the Heart Subcommittee meeting minutes from October 23, November 6, and December 4, 2014, and January 22 and March 26, 2015.

5. Changes to Heart-Lung Allocation Policy

*Public Comment: January, 2016 (Estimated)*

*Board Consideration: June, 2016 (Estimated)*

The Heart Subcommittee is delaying its conversations regarding heart-lung allocation policy modifications until after the new adult heart allocation tiers are designed. If feasible, the Heart Subcommittee will develop a proposal in time for public comment along with the proposed changes to the adult heart allocation scheme. Until then, the [guidance document](#) approved by the Board of Directors in November, 2014 will continue to help OPOs allocate heart-lung blocs in accordance with *Policy 6.5.E: Allocation of Heart-Lungs*.

6. Allocation of Deceased Donor Lungs that Have Undergone Ex Vivo Lung Perfusion

The Thoracic Committee previously decided not to recommend changes to lung allocation policy despite the introduction of EVLP technology to market, and continues to support this position. The Committee is awaiting 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**

7. Pediatric Heart Policy Modifications

*Public Comment: [March – June, 2013](#)*

*Board Approval: [June 2014](#)*

*Implementation Date:* Work on this project is expected to begin in the fall of 2015 and implementation is anticipated in the first quarter of 2016.

The Pediatric Heart Allocation Modification changes to the qualifying criteria for the medical urgency statuses, expands the qualifying criteria for ABO-incompatible (ABO-i) heart transplantation, modifies the prioritization of candidates eligible for ABO-i heart transplants, and eliminates the ability to register an *in utero* heart candidate.

### **Implemented Committee Projects**

8. Lung Allocation Score (LAS) Modifications

*Public Comment: [March – June 2012](#)*

*Board Approval: [November 2012](#)*

*Implementation Date: February 19, 2015*

Modifications to the LAS were successfully implemented on February 19, 2015. UNOS staff provided the community with a content webinar, focused on policy changes, and a systems

training, focused on changes to UNet<sup>SM</sup>, to prepare the community for these changes. This outreach proved valuable, as members experienced a largely smooth post-implementation transition. Questions from the community were promptly answered and are [posted as a “frequently asked questions” document](#) on the OPTN website.

The Thoracic Committee will review the early results of the LAS implementation during its June 11, 2015 meeting and include information for the December 2015 Board meeting.

9. LAS of 50 or Higher Clarification

*Public Comment:* [March – June, 2011](#)

*Board Approval of Clarification:* [November 2014](#)

*Implementation Date:* February 1, 2015

In November 2014, the Board of Directors approved clarifications to the Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher. The clarifications are intended to help transplant programs understand the reporting requirements for candidates with a lung allocation score (LAS) of 50 or higher, and will also help the Department of Member Quality monitor the policy consistently. UNOS staff is also working on a document to further clarify the policy for transplant programs.

10. Pediatric Lung Adolescent Classification Exception

*Public Comment:* [March – June, 2014](#)

*Board Approval:* [June 2014](#)

*Implementation Date:* July 1, 2014

The Thoracic Committee continues to monitor the number of pediatric lung candidates requesting an exception to be registered as an adolescent candidate for the purposes of offers from adolescent and adult deceased donors. As of April 17, 2015, 14 candidates received approval for the adolescent classification exception. These candidates were registered at seven different transplant programs. Two of the candidates had two adolescent classification exceptions. A total of three candidates with adolescent classification exceptions were added to the waiting list in 2015.

**Review of Public Comment Proposals**

The Committee reviewed 10 of the 17 proposals released for public comment from September 29 – December 5, 2014.

11. Clarification of Multi-Organ Policies (Policy Oversight Committee)

The Thoracic Committee reviewed this proposal and did not have any questions or concerns.

12. Proposal to Clarify the Definition of Organ Transplant and Transplant Date (Policy Oversight Committee)

The Thoracic Committee reviewed this proposal and did not have any questions or concerns.

13. Proposal to Allow Collective Patient and Wait Time Transfers (Operations and Safety Committee)

The Thoracic Committee reviewed this proposal and supports it. In response to the specific requests for comment, the Thoracic Committee believes the 90-day post-transfer report

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requirement is appropriate to encourage transplant hospitals to communicate with candidates about their status on the waiting list.

### 14. Definition of a Transplant Hospital (Membership and Professional Standards Committee)

The Thoracic Committee reviewed this proposal and supports it. They believe it makes sense and they understand why such a definition is necessary.

### 15. Establishing a Quality Assessment and Performance Improvement Requirement for Transplant Hospitals and Organ Procurement Organizations (Membership and Professional Standards Committee)

The Thoracic Committee reviewed this proposal and supports it. The Committee commented that the QAPI requirements should align with CMS requirements to the extent possible so that transplant hospitals and OPOs do not have to adhere to separate quality standards and processes. The Thoracic Committee suggested explicitly including language in the policy that the OPTN/UNOS requirements will not be duplicative of CMS requirements. The Thoracic Committee otherwise agrees that quality should be woven into transplant culture just as it is woven into other aspects of medical care.

### 16. Improving the OPTN Policy Development Process (Executive Committee)

The Thoracic Committee reviewed this proposal and supports it.

### 17. Implementing Pre-Transplant Performance Review by the Membership and Professional Standards Committee

The Thoracic Committee reviewed this proposal and generally supports it. The Committee agrees it is reasonable to examine these metrics to ask questions about a program that is not transplanting at expected rates. The Committee is concerned about the punitive tone of the proposal and policy language and suggests that in the spirit of using these metrics as a tool to identify programs for process improvement, the language should reflect this purpose in a positive tone. The Committee is also concerned about the effect these metrics may have on a program's willingness to waitlist higher risk patients in the future. These metrics may deter innovative practices that require some risk if they are too restrictive. Finally, the Committee recommended that these metrics not be made public.

### 18. Addressing the Requirements Outlined in the HIV Organ Policy Equity Act (Organ Procurement Organization Committee)

The Thoracic Committee reviewed this proposal and did not have any questions or concerns. They noted it is the responsibility of the OPTN/UNOS to establish necessary safeguards to prevent HIV positive organs from accidentally being transplanted into recipients that are not HIV positive.

### 19. VCA Implementation (Vascularized Composite Allograft Transplantation Committee)

The Thoracic Committee reviewed this proposal and did not have any questions or concerns.

### 20. Policy Rewrite Parking Lot Quick Fixes (Policy Oversight Committee)

The Thoracic Committee reviewed this proposal and did not have any questions or concerns.

The Committee reviewed six of the 10 proposals released for public comment from January 27 – March 27, 2015.

**21. Proposal to Require Re-Execution of the Match Run When a Deceased Donor's Infectious Disease Results Impact Potential Recipients Based upon Screening Preferences (Ad Hoc Disease Transmission Advisory Committee)**

The Thoracic Committee agreed this is a well-thought out proposal with a sound solution.

**22. Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act (Organ Procurement Organization Committee)**

The Thoracic Committee questioned what safeguards will be in place to prevent inadvertent placement of thoracic organs from HIV+ donors into HIV- recipients. The OPO Committee representative explained that only transplant centers with IRB approval will be permitted to list their kidney and liver candidates to receive organs from HIV+ donors, and thoracic candidates will not appear on any of these match runs.

**23. Clarify Policy Language and Process for Individual Wait Time Transfer (Patient Affairs Committee)**

The Thoracic Committee determined this is a well-considered policy. The Committee questioned whether the requirement that the transplant center communicate to the candidate that the wait time has been transferred is something that can be monitored. The Patient Affairs Committee staff liaison ensured the Thoracic Committee that this proposal can be monitored.

**24. Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws (Pediatric Transplantation Committee)**

After reviewing the proposal, the Thoracic Committee voiced a number of concerns. First, the experience for the heart and lung programs is disparate. The data show that 20 out of 42 lung transplant centers would not currently meet criteria. This is disconcerting because a number of these programs might be performing transplants for adolescent lung recipients. The Thoracic Committee therefore believes this policy might have a negative impact on adolescent candidates and decrease their access to transplant. One Thoracic Committee member did point out that the maps showing the number of centers that would qualify under the new bylaws are based on center volumes not surgeon volumes, and that the bylaws for surgeon volumes will be much easier to meet.

Some members of the Thoracic Committee also do not find the data showing the relationship between outcomes and experience to be compelling, and argued that the data reveal a relationship between outcomes and volumes in infants, not all pediatric patients less than 18. One member of the Committee explained that the data cannot show the relationship between outcomes and volumes for lungs because the number of cases is too small, but the data showing the relationship between outcomes and volumes in other organs is convincing. Adolescents in particular have the highest risk of rejection, non-compliance, and shortest graft survival, and they therefore require a transplant team that is experienced in handling adolescent cases. The bylaws should therefore focus more on center volume instead of surgeon volume.

Another Thoracic Committee member expressed concern about the number of highly trained pediatric pulmonologists and the potential number of pediatric lung transplant programs. Centers will be required to hire a pediatric pulmonologist, but there are insufficient pediatric pulmonologists trained in transplantation. Additionally, there may be centers that would hire a pediatric pulmonologist that would only be performing adolescent, not infant, transplants anyway. While pediatric transplantation teams are very important, it is also important that the patient is cared for by experienced surgeons and physicians.

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The Thoracic Committee suggested that the age cut-off of 18 is not appropriate. The Committee suggested there are ways to justify an age cut-off lower than 18, perhaps based on size/weight or the ability to perform certain technical procedures on the patient. Even if these bylaws apply to all programs treating all candidates less than 18, the Committee suggested including an exception in the bylaws, albeit an exception with limited application so that it doesn't become the norm.

### **25. Proposal to Improve UNetSM reporting of Aborted Procedures and Non-Transplanted Organs (Living Donor Committee)**

The Thoracic Committee reviewed this proposal because of its potential impact on living lung donors, but did not have any comments.

### **26. Proposed ABO Blood Type Determination, Reporting and Verification Policy Modifications (Operations & Safety Committee)**

The Thoracic Committee reviewed this proposal and did not have any comments.

## **Other Committee Work**

### **27. Email from a Member Regarding CardioMEMS**

A member of the transplant community emailed the Committee to inquire whether an individual being monitored with the CardioMEMS device should be considered to require "continuous hemodynamic monitoring of the left ventricular filling pressures" for the purposes of meeting Status 1A. The Subcommittee reviewed current policy, which requires candidates to be admitted to the transplant hospital that registered the candidate on the waiting list, and the candidate "requires continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, and requires continuous hemodynamic monitoring of the left ventricular filling pressures."

The Subcommittee agreed that using the CardioMEMS device to monitor the candidate's pressures does not meet the spirit of the status 1A policy, which is to prioritize those candidates that are most unstable and at imminent risk of death. However, the policy is not written in a way that would preclude those monitored with CardioMEMS from registering as status 1A. Nevertheless, to meet this status 1A criterion these candidates must also be admitted to the hospital that registered them on the waiting list, and it is likely that those candidates that are monitored with CardioMEMS will be in an ambulatory setting and not admitted to the hospital, and therefore would not qualify for status 1A.

## **Meeting Summaries**

The committee held meetings on the following dates:

- November 21, 2014
- December 18, 2014
- March 19, 2015
- April 9, 2015

Meetings summaries for this Committee are available on the OPTN website at: <http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=5>.