

OPTN Thoracic Organ Transplantation Committee

Meeting Summary

May 28, 2020

Conference Call

Ryan Davies, MD, Chair
Erika Lease, MD, Vice Chair

Introduction

The Thoracic Organ Transplantation Committee met via Citrix GoToMeeting teleconference on 05/28/2020 to discuss the following agenda items:

1. Public comment review: Update of Lung Allocation Score (LAS) Cohort
2. Public comment review: Guidance for Adult Heart Status 2 Exception Requests and Policy Modifications
3. Public comment review: Guidance for Pediatric Heart Exception Requests

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

1. Public comment review: Update of Lung Allocation Score (LAS) Cohort

UNOS Staff provided an overview of the LAS Cohort Update policy proposal and asked the committee to vote to approve the policy moving to public comment starting August 4th, 2020.

Summary of discussion:

UNOS Staff shared that the policy seeks to:

- Remove the following covariates from the waitlist mortality model
 - Bilirubin increase of at least 50%
 - Cardiac index
 - Central venous pressure (CVP)
 - Diabetes
 - Forced vital capacity (FVC)
 - Eisenmenger's Syndrome diagnosis
 - Lymphangioleiomyomatosis diagnosis
 - Obliterative bronchiolitis (not-retransplant) diagnosis

- Remove the following covariates from the post-transplant mortality model
 - Creatinine increase of at least 150%
 - Functional status
 - Eisenmenger's Syndrome diagnosis
 - Lymphangioleiomyomatosis diagnosis
 - Pulmonary fibrosis, not idiopathic diagnosis

This information will continue to be collected for analytical purposes. Coefficients of remaining covariates will be updated based on March 1, 2015- March 31, 2018 cohort. Corresponding definitions and probability data will also be updated.

Currently, the cohort being used to calculate LAS is more than ten years old.

UNOS Staff showed the committee the changes described above to Table 10-1 on the draft policy document.

The Chair noted that when the models were recalculated using the more recent cohort, the data points listed above were no longer statistically significant which is what prompted this policy proposal.

UNOS Staff asked the committee if there were any questions. There were no questions asked.

The committee members voted and approved submitting the LAS update policy proposal to public comment starting August 4th and ending October 1st via Poll Everywhere (15 yes; 0 no; 0 abstain).

2. Public comment review: Guidance for Adult Heart Status 2 Exception Requests and Policy Modifications

UNOS Staff and the Chair of the Heart Subcommittee gave an overview of the Guidance and Policy Clarifications Addressing Adult Heart Allocation policy proposal and asked the committee to vote to approve the guidance and policy revisions moving to public comment starting August 4th, 2020.

Summary of discussion:

The Chair of the Heart Subcommittee shared that the policy proposal was created in response to the heart allocation policy implemented in October 2018. Post-implementation analysis found that there was a notable increase in Status 2 exception requests. This raised concerns around whether certain therapies were at risk of being used as a stepping stone to qualify candidates for higher statuses. The clinical narratives of 200 adult heart exception requests were read. They revealed opportunities to improve the information provided in clinical narratives to allow Regional Review Boards to make more informed decisions. This led to creating a template as part of the guidance to provide the Regional Review Boards with pertinent data in a unified way. The template includes sections for a clinical description of the patient, factors impacting inability to wean the patient, and applicable contraindications to LVAD.

The Chair of the Heart Subcommittee gave an overview of the draft policy revisions that include modifications to the following policies.

6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device

- The policy change is to reduce the days at status from 14 to 7 in order to better align the status with the highest medical urgency.

6.1.C.vi: Mechanical Circulatory Support Devices (MCS) with Device Infection

- Reorder Table 6-1 so similar criterion are listed together
 - Relocating “positive culture of materials from the pump pocket of an implanted device”
 - No change in content

6.1.D.ii: Inotropes without Hemodynamic Monitoring

- Replace date of form submission with date of inotropic administration for when cardiac index criteria must be met to increase clarity
- Increase number of days from 90 to 180 for both initial stay and extension to better match clinical practices

UNOS Staff asked the committee if there were any questions. There were no questions asked.

The committee members voted and approved submitting the draft guidance and policy language to public comment starting August 4th and ending October 1st via Poll Everywhere (13 yes; 0 no; 0 abstain).

3. Public comment review: Guidance for Pediatric Heart Exception Requests

UNOS Staff explained that the proposed guidance for pediatric heart exception requests is intended to accompany the National Heart Review Board for Pediatrics proposal that is going to the Board for approval on June 8th. The Chair gave an overview of the draft guidance and asked the committee to vote to approve the guidance moving to public comment starting August 4th, 2020.

Summary of discussion:

The Chair shared that the guidance was developed by the Pediatric Heart Workgroup. The Workgroup also received comments from Advanced Cardiac Therapies Improving Outcomes Network (ACTION Network), a collaborative also examining ways to improve clinical outcomes for children with heart failure.

The guidance provides further criteria for pediatric patients with the following conditions who are seeking Status 1A and 1B exceptions:

- Dilated cardiomyopathy
- Restrictive or hypertrophic cardiomyopathy
- Single ventricle heart disease
- Coronary allograft vasculopathy and retransplantation

The Chair asked the committee if there were any questions. There were no questions asked.

The committee members voted and approved submitting the guidance for pediatric heart exception request proposal to public comment starting August 4th and ending October 1st via Poll Everywhere (15 yes; 0 no; 0 abstain).

UNOS Staff reported that all three proposals had 100% votes to approve and thanked the committee.

The departing committee members, Ryan Davies, Matt Hartwig, and Tania Sherrod, were thanked for their time and dedication.

Upcoming Meetings

- June 18, 2020: Continuous Distribution of Lungs Workgroup (teleconference) – 5:00 to 6:00 pm (EDT)
- June 25, 2020: Heart Transplantation Subcommittee (teleconference) – 5:00 to 6:00 pm (EDT)
- July 16, 2020: Lung Transplantation Subcommittee (teleconference) – 5:00 to 6:00 pm (EDT)
- July 21, 2020: Heart Transplantation Committee (teleconference) – 5:00 to 6:00 pm (EDT)
- August 18, 2020: Heart Transplantation Committee (teleconference) – 5:00 to 6:00 pm (EDT)
- August 20, 2020: Lung Transplantation Subcommittee (teleconference) – 5:00 to 6:00 pm (EDT)