



The Society of Thoracic Surgeons

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October 18, 2016

Liz Robbins Callahan
Policy Manager
United Network for Organ Sharing
700 North 4th St
Richmond, VA 23219

Sent via email

Re: Proposal to Modify the Adult Heart Allocation System

Dear Ms. Callahan:

On behalf of The Society of Thoracic Surgeons (STS), thank you for the opportunity to provide comments on the revised Proposal to Modify the Adult Heart Allocation System. Founded in 1964, STS is an international not-for-profit organization representing more than 7,000 cardiothoracic surgeons, researchers, and allied health care professionals in 90 countries who are dedicated to ensuring the best surgical care for patients with diseases of the heart, lungs, and other organs in the chest. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

The Thoracic Organ Transplantation Committee has proposed important revisions to the Proposal to Modify the Adult Heart Allocations System. The goal of the revised document is aimed to: 1) better stratify the most medically urgent heart transplant candidates, 2) reflect the increased use of mechanical circulatory support devices (MCS) and prevalence of MCS complications, and 3) address geographic disparities in access to donors among heart transplant candidates.

STS applauds the OPTN/UNOS Thoracic Organ Committee's efforts to improve the equity of the current heart allocation system in the United States. The proposed revisions to the Proposal to Modify the Adult Heart Allocation System address previous concerns related to priority assignment and allocation. The STS addresses the following questions raised by the OPTN/UNOS Thoracic Organ Committee.

Are the proposed indicators of cardiogenic shock appropriate?

The OPTN/UNOS Thoracic Committee has proposed imposing additional criteria for initially qualifying for status 1 under the VA ECMO criterion, status 2 under the percutaneous device and IABP criteria and status 3 under multiple inotropes with hemodynamic monitoring criterion. The proposal requires hemodynamic assessment within 7 days prior to administration of

October 18, 2016

Ms. Callahan

2

these therapies that the candidate's systolic blood pressure be less than 90 mmHg, pulmonary capillary wedge pressure be greater than 15, and cardiac index be either less than 1.8 L/min/m if the candidate is not supported by inotropes or less than 2.2 L/min/m if the candidate is supported by inotropes. For those candidates whose hemodynamic measurements cannot be obtained within 7 days prior to support, then within 24 hours prior to support either the candidate's systolic blood pressure must be less than 70 mmHg, arterial lactate must be greater than 4 mmol/L, aspartate transaminase (AST) or alanine transaminase (ALT) must be greater than 1,000 U/L, or CPR must have been performed on the candidate.

RESPONSE: The STS supports the inclusion of the hemodynamic assessment as criteria for qualifying for status 1 under the VA ECMO criterion, status 2 under the percutaneous device and IABP criteria and status 3 under multiple inotropes with hemodynamic monitoring criterion. Although no definition of cardiogenic shock is without important limitations, the STS believes the addition of this hemodynamic assessment will reduce inappropriate utilization of these therapies to justify higher urgency status. However, the STS believes that hemodynamic assessment alone is inadequate to define cardiogenic shock and that additional criteria should be added to the hemodynamic assessment to reflect and document the clinical presence of tissue malperfusion.

The STS supports the decision to limit urgent status to 14 days and require transplant programs to apply to the regional review board to extend a candidate's registration after their initial period if they are supported by VA ECMO, acute circulatory support devices, non-dischargeable LVADs or intra-aortic balloon pumps, and that the transplant program must provide the Regional Review Board (RRB) with evidence that the candidate has a contraindication to being transitioned to durable support and objective evidence of failure to wean the candidate off the current support.

Should regional review boards review cases from other regions instead of their own regions?

RESPONSE: The STS supports the proposed procedure of Regional Review Boards reviewing cases from other regions instead of their own region. The STS believes this will ensure more objective and uniform practice across UNOS regions.

Should the current policy for sensitized candidates (permitting the transplant programs and OPO in the donation service area to agree to allocate a donor heart to a sensitized candidate even if the candidate is not first on the match run) remain in place in light of broader sharing?

RESPONSE: The STS supports permitting transplant programs and Organ Procurement Organizations in the domain service area to agree to allocate a donor heart to a sensitized candidate even if the candidate is not first on the match run with the added provisions that: 1) the proposal adds a restriction that the heart may be allocated out of sequence within the DSA but only within a status; 2) the proposal requires members to submit additional data on sensitization status; and 3) the proposal to permit a sensitized candidate within the DSA to be prioritized for

October 18, 2016

Ms. Callahan

3

offers is done so to the extent that the candidate would not receive offers ahead of a candidate in Zone A that would otherwise be registered before the candidate.

Comment to Policy 6.3.A: RRB and Committee Review of Status Exceptions:

The STS supports the continued retrospective review of Exceptions for candidates in the highest urgency statuses. This policy proposal maximizes benefit to the waitlist candidate and takes into consideration the delays a policy of prospective review would have on transplantation for the waitlist candidate. The STS supports UNOS Thoracic Organ Committee review of transplants not determined to be warranted by the Regional Review Board and referral to the Membership and Professional Standards Committee.

Which data elements on the list of potential heart allocation score data are likely to be incorporated into a heart allocation score due to their potential to predict waiting list mortality or post-transplant survival?

- *Are there additional data elements that should be collected which the Committee did not include?*
- *Are there extraneous data elements on the list?*
- *Are there any data elements that should only be collected on VAD patients?*

Appendix B: List of Data Elements that May Be Predictive of Waiting List Mortality or Post-Transplant Survival and References.

List of Data Elements that May Be Predictive of Waiting List Mortality or Post-Transplant Survival
Hemodynamic Data
Central Venous Pressure (CVP)
Pulmonary Artery Systolic Pressure (PASP)
Pulmonary Artery Diastolic Pressure (PADP)
Pulmonary Capillary Wedge Pressure (PCWP)/LVEDP
Cardiac Output
Cardiac Index
Systolic Blood Pressure (SBP)
Diastolic Blood Pressure (DBP)
Invasive pulmonary artery catheter or daily hemodynamic monitoring to measure cardiac output and left ventricular filling pressures?
Were hemodynamic values obtained while the patient was on support?
Vital Signs Date
Resting Heart Rate (on same date as hemodynamic tests)
Mixed venous oxygen saturation (with hemoglobin)
Exercise Testing/Functional Status
Cardiopulmonary Stress Test Date

October 18, 2016

Ms. Callahan

4

Peak O2 Consumption
RER
VE/VCO2
Six Minute Walk Test Results
Heart Failure Severity/End Organ Function
Sodium
Creatinine
Dialysis and type
BUN
Albumin
Serum Total Bilirubin
Serum Glutamic Oxaloacetic Transaminase (SGOT)
Brain Natriuretic Peptide (BNP) (specify)
International Normalized Ratio (INR) (and specify Warfarin)
Arterial lactate
Number of hospital admissions for heart failure over last 12 months
Heart Failure Therapies
Diuretic Dose/frequency
Detailed Inotrope Use
Anti-Arrhythmics
Continuous Mechanical Ventilation
Pulmonary Vasodilators
Sensitization Data
CPRA
PRA Typing Method
MFI Threshold
Operative Risk
Number of Prior Sternotomies

RESPONSE: The STS supports the attempt of the UNOS Thoracic Organ Committee to obtain additional data to develop a heart allocation score as a basis for determination of priority for listing. This is a difficult process as the complexity of patients presenting for heart transplantation varies significantly. Many of the above data elements assessing functional status such as 6 minute walk test distance and peak exercise oxygen consumption study are likely to have limited relevance for a candidate on acute forms of temporary circulatory support or ECMO. Assessments of the stability of hemodynamics and adequacy of tissue perfusion such as arterial lactate are likely to be of more significance for candidates on temporary mechanical circulatory support. Functional assessments may be of greater value to determining priority for candidates not on acute forms of circulatory support.

October 18, 2016

Ms. Callahan

5

Additional data elements to consider to include for risk assessment;

1. Heart rate at the time of hemodynamic assessment
2. Indices to assess right heart function such as right ventricular stroke work index and pulmonary artery index
3. Number of ICD discharges within the previous 6 months
4. Percent lymphocyte count
5. Serum uric acid level
6. Presence of congenital anatomy and type
7. Assessments of frailty
8. Assessments of nutrition; e.g., serum prealbumin
9. Assessments of pulmonary function

Thank you for the opportunity to share our thoughts on the Committee's proposal to ensure that transplant candidates receive the highest quality care. If you have any additional questions, please contact Courtney Yohe, STS Director of Government Relations, by phone at 202-787-1222 or by e-mail at cyohe@sts.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph E. Bavaria". The signature is fluid and cursive, with a long horizontal stroke at the end.

Joseph E. Bavaria, MD
President