The Society of Thoracic Surgeons

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

Re: Proposed Changes to the OPTN/ UNOS 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 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 modifications to the adult heart allocation system to: 1) better stratify the most medically urgent heart transplant candidates, 2) reflect the increased use of mechanical circulatory support devices (MCSD) and prevalence of MCSD 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 and agrees that the current allocation system has substantive issues with respect to assignment of priority and geographic access to donor organs. However, while recognizing that any change in the allocation system will still have limitations, we have outlined below a number of significant issues with the proposed revisions.

1. Assignment of Extracorporeal Membrane Oxygenation (ECMO) to Status 1 Priority

The Society believes that assigning highest priority to candidates on mechanical circulatory support with ECMO is justified. However, without requiring medical justification to limit the use of ECMO as a bridge to transplantation, we fear this strategy will have a significant adverse effect on both wait-list mortality and post-transplant mortality for this group of

candidates. The thoracic simulation allocation model (TSAM) analysis projected that, under the proposed six-status system and broader sharing scheme, an average of 31 candidates would be transplanted on ECMO. Without requiring additional medical justification, STS believes that the assignment of ECMO to the highest priority will significantly influence clinical practice and drive more clinicians to utilize ECMO (over other mechanical circulatory support options) as a bridge to heart transplantation than predicted by the TSAM analysis. STS believes that the overall benefit predicted by the TSAM analysis in terms of reduction in waitlist mortality and improvement in post-transplant survival will be adversely impacted by larger number of candidates both waiting and transplanted while on ECMO support than predicted by the TSAM analysis.

STS believes that ECMO is a satisfactory means to bridge candidates to heart transplantation in a small minority of clinical scenarios and that alternative options exist in the overwhelming majority of cases. Therefore, we would suggest that additional medical justification and documentation of absence of other alternative options be required to ensure that limited numbers of candidates would be eligible for this strategy for priority listing.

2. *Discretionary Assignment of 30 Days of Status 3 Urgency to stable LVAD Candidates*

Under the new allocation system, candidates stable on dischargeable left ventricular assist device (LVAD) support would be assigned status 4 urgency. However, the proposed allocation system permits the discretionary assignment of 30 days of status 3 urgency time to candidates who are stable on support with a dischargeable LVAD. It is unclear if the TSAM analysis modeled zero days of elective discretionary time and determined what adverse impact, if any, this would have had on overall waitlist and post-transplant mortality. The assignment of discretionary status 3 time to candidates stable on LVAD support appears contrary to the aims of the proposed revisions and does not appear equitable.

However, we are also aware that candidates stable on LVAD support have a: 1) high rate of readmissions within one year of LVAD implant (80% of patients readmitted within 1 year in the recently published ROADMAP Study (JACC 2015); and 2) high ongoing risk of stroke, gastrointestinal bleeding and pump thrombosis. Removing the 30 days of discretionary time may lead to a reduction in rates of transplantation for stable dischargeable LVAD candidates at status 4 urgency and increase the morbidity and mortality of this group. STS suggests that additional TSAM analysis may be required so that the Thoracic Organ Transplantation Committee can make an informed decision.

3. *Geographic Allocation of Heart Donors*

Although STS agrees with the proposal to eliminate the donation service area (DSA) as a unit of allocation, we believe that donor organs should not be allocated to zone B without prior allocation of donor organs to more urgency statuses within zone A. We believe that

allocation of more organs to zone B would increase the ischemic time of donor organs and increase post-transplant mortality. We do not believe the extent of this adverse effect was adequately modeled in the TSAM analysis. Instead, donor organs should be allocated to candidates within zone A to candidates within status 1, 2, 3 and possibly 4 prior to allocation to zone B.

4. *Multi-organ Transplants*

   STS believes that multi-organ transplants have been assigned too low a priority. Candidates, particularly those awaiting heart and liver transplantation, lack sufficient alternative treatment options in many instances and will be adversely biased in the proposed allocation system. Under the current allocation system, multi-organ transplants from non-local organ procurement organizations have different priorities for the second organ. This issue requires further clarification in the proposed new allocation system.

5. *Candidates with Ischemic Heart Disease with Intractable Angina*

   STS believes that further justification above objective evidence of ischemic heart disease is necessary for candidates with intractable angina to justify status 4 listing. Angina or objective evidence of ischemia alone provides insufficient evidence for poor prognosis and other measures of risk should be required.

6. *Candidates with MCSD with Hemolysis*

   The proposed allocation system requires that candidates must fail one attempt at intravenous therapy for treatment of hemolysis to quality for this complication for higher urgency listing. STS believes that further clarification is needed as to what intravenous therapies are acceptable and what constitutes failure under the proposed allocation system.

7. *Clarification of the Terminology "Non-dischargeable BiVAD or RVAD"*

   Table 3 in the OPTN/UNOS document lists "non-dischargeable BiVAD or RVAD" configuration as meeting criteria for status 1 listing. On page 13 of the document, "non-dischargeable VAD" is used to describe criteria for status 1 listing. It should be changed and clarified that BiVAD or RVAD support is required for status 1 listing and "non-dischargeable VAD" not simply represent "non-dischargeable LVAD". Status 2ii in Table 3 should be clarified to read "non-dischargeable LVAD only" and not "acute circulatory support device" to distinguish those patients requiring BiVAD or RVAD support from those candidates requiring LVAD support only. STS believes that candidates on "non-dischargeable" BiVAD or RVAD support are at higher risk of waitlist mortality than candidates on "non-dischargeable" LVAD support only and appropriately should be given higher priority.

8. Sensitized Candidates

Although not addressed in the proposed allocation system, STS believes that sensitized candidates be allocated a higher urgency status. For example, STS proposes that candidates with a CPRA of 25 to 50% be assigned to status 4 and candidates with a CPRA of >50% be assigned to status 3.

Responses to the specific questions raised by the OPTN/UNOS Thoracic Organ Committee:

- Do you support the proposed status criteria?

  STS does not support the status criteria as currently proposed.

- Do you support the proposed geographic sharing scheme? Do you support the retention of the DSA as a unit of allocation for hearts?

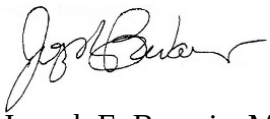
  STS does not support the geographic sharing scheme as currently proposed. STS does not continue to support the DSA as a unit of allocation for hearts.

- Do you support the concept of requiring CPRA to be entered for candidates upon registration and removal?

  STS supports the concept of requiring CPRA to be entered for candidates upon registration and removal.

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,



Joseph E. Bavaria, MD
President