



ISHLT

A Society that Includes Basic Science, the Failing Heart, & Advanced Lung Disease

ISHLT Response to OPTN Update on Continuous Distribution of Hearts

The International Society for Heart and Lung Transplantation (ISHLT) appreciates the opportunity to provide feedback on the “Update on Continuous Distribution of Hearts” OPTN public comment. ISHLT applauds the Heart Transplantation Committee for their work thus far in restructuring the current heart allocation system into a continuous distribution system.

ISHLT agrees with all proposed attributes for inclusion in the first iteration of the heart transplant continuous distribution. Recognizing medical urgency weighs most heavily on heart allocation, ISHLT would like to highlight concerns with the current 6 tier allocation system in an effort that these be addressed during further development of medical urgency criteria. We believe it is imperative to improve access to transplant for certain candidates beyond what is offered to them in the current allocation system and are requesting more granularity for certain patient populations.

ISHLT strongly believes the updated continuous distribution system needs to address the fact that LVAD patients with complications have high waitlist mortality and delisting rates that are not accounted for in the current 6 tier status system. The current statuses for LVAD patients do not adequately capture their degree of illness. According to the OPTN Four-year Monitoring of Heart Allocation Report, an LVAD patient with right heart failure or hemolysis, currently both considered a UNOS status 3, have more than double the mortality rate of a status 2 patient on Intra-Aortic Balloon Pump (IABP) (20 & 18 vs. 9 deaths per 100 patient years).¹

Another analysis reveals there is an approximately 50% 1-year mortality or delisting rate for BTT LVAD patients if inotrope is needed over 1 month post implant.² Durable LVAD patients with complications need to have an accelerated path to heart transplant with urgency criteria similar to those on endovascular tMCS with anatomical suitability for durable LVAD.

ISHLT also believes that an LVAD patient with multiple adverse events (i.e. stroke, GI bleed, infection, device malfunction) should be able to obtain subsequent escalation in medical urgency points. Survival beyond 1 year post LVAD implant decreases as the number of episodes of right heart failure, stroke, GI bleeding, device malfunctions, and infections increase within the first year post implant. For example, per each episode of stroke within the first year post implant, adjusted mortality increased 42% in those alive at 1 year and by 24% for those alive on support at 3 years. Additionally, for each episode of stroke, major infection, and device malfunction in the first 3 years of LVAD support lead to worse extended survival.³ Cumulative complications on LVAD should lead to an equivalent number of medical urgency priority points based on this higher mortality rate. Separately, we agree LVAD patients who have an uncomplicated course should receive an annual increase in percentage points as is written in the proposal.

Upon review of Table 4 in the proposal, ISHLT is concerned many of the diagnoses grouped together are not of similar medical urgency. Current Status 2 patients have an extremely varied rate of mortality depending on criteria. We cannot justify listing a patient with IABP at the same medical urgency as a patient with a BiVAD/RVAD when the mortality for the latter is more than double (9 deaths per 100 years vs. 26 deaths per 100 years).¹ This can be resolved by separating certain criteria out within the current statuses and assigning percentage points in line with current mortality data. Additionally, for current status 2 patients, we can consider further modifying hemodynamic criteria or requiring proof of



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failure of inotropic support prior to placement of tMCS. We understand the medical urgency groupings in this proposal are an early attempt and look forward to reviewing this after further statistical analysis.

In light of the recent publication in JAMA, "Development and Validation of a Risk Score Predicting Death Without Transplant in Adult Heart Transplant Candidates" by Zhang et al., the Committee should consider the US-Candidate Risk Score when further developing the medical urgency attribute of the heart continuous allocation.⁴ This model had significantly higher sensitivity for predicting waiting list death and higher specificity for predicting waitlist survival than the current 6 status system. This may help to further inform us on separation of medical criteria within the current statuses and to create a more equitable spread in terms of risk.

In response to the questions posed in the update:

1. *Should candidates assigned to adult heart status 4 using the LVAD criterion be allowed to receive a higher percentage of medical urgency priority points than candidates assigned to the highest medical urgency rating groups, such as candidates on VA ECMO?*

ISHLT believes that although this question is unclear as to its intent, given the rigidity of the question, our answer is Yes. We believe that if the mortality of cumulative complications on an LVAD outweigh the mortality of a patient on VA ECMO, then the patient should be able to receive a higher percentage of medical urgency priority points than candidates assigned to the highest medical urgency rating groups. As previously stated, ISHLT believes the heart transplantation committee needs to take into consideration the aforementioned mortality rates for VAD patients with adverse events.

2. *Are the attributes the Committee has identified for inclusion in the first version of the continuous distribution of heart allocation framework appropriate? Do you agree with the Committee's decision to include each attribute in the first version of Heart CD? Why or why not?*

ISHLT supports the inclusion of all mentioned attributes in the first version of Heart CD and believes there is sufficient data available for each of the mentioned attributes.

3. *Are there other attributes that the Committee should consider when developing the first version of the continuous distribution of heart allocation framework, and why? What data analysis of information is available to support their inclusion?*

ISHLT supports all attributes the committee has considered for the first version of continuous distribution. Please consider our previous suggestions regarding medical urgency criteria that are mentioned above.



4. *Considering the individual attributes, what information should the Heart Committee use to evaluate success toward the outcome of that specific attribute?*

The medical urgency attribute should evaluate waitlist mortality and post-transplant survival to evaluate success.

5. *Are there any allocation factors or attributes in current heart allocation policy that should not be included in the first version of continuous distribution? Why?*

None.

6. *From the patient, donor, family perspective, what do you consider to be the most key factors for allocating donor hearts?*

ISHLT encourages the OPTN to create educational primers to allow for simplified understanding of what is included in the heart continuous distribution proposal. Educational sessions and patient-focused materials would allow for more input on heart continuous distribution from the patient perspective.

References

1. OPTN Descriptive Data Request, “Four-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System,” Prepared for OPTN Heart Transplantation Committee Meeting, March 29, 2023
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2. Rali, A. S., Inampudi, C., Zalawadiya, S., et al. Changing Strategy Between Bridge to Transplant and Destination LVAD Therapy After the First 3 Months: Analysis of the STS-INTERMACS Database. *Journal of Cardiac Failure*. 2023; S1071-9164(23)00371-8.
3. Hariri, I. M., Dardas, T., Kanwar, M., et al. Long-term survival on LVAD support: Device complications and end-organ dysfunction limit long-term success. *The Journal of Heart and Lung Transplantation: the official publication of the International Society for Heart Transplantation*. 2022; 41(2), 161–170.
<https://doi.org/10.1016/j.healun.2021.07.011>
4. Zhang KC, Narang N, Jasseron C, et al. Development and Validation of a Risk Score Predicting Death Without Transplant in Adult Heart Transplant Candidates. *JAMA*. 2024;331(6):500–509. doi:10.1001/jama.2023.27029

ISHLT Level of Support: Strongly Support the Policy