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RESEARCH CORRESPONDENCE

Potential impact of a shock requirement on adult heart allocation

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A cardiogenic shock requirement was recently added to the now accepted 6-Status Heart Allocation System (Figure 1).[1] The criteria, derived from the American Heart Association standards for cardiogenic shock, were designed to prevent non-urgent candidates from qualifying for high priority Status based on therapies alone.[1] Although the original proposal has undergone extensive simulation, those prediction models were estimated before the addition of the cardiogenic shock criteria.[2] Therefore, the number of candidates the shock criteria would cause to list at a lower priority Status was not quantified, and the effect of the shock criteria on overall allocation was not estimated. We aimed to determine the proportion of candidates impacted by the requirement and examine the ability of the shock criteria to predict transplant-free waitlist survival.

The registrations of all adult heart-only candidates listed during the years 2010–2015 were analyzed using the Scientific Registry of Transplant Recipients (SRTR) data set. Candidates subject to the shock criteria include candidates supported with venoarterial extracorporeal membrane oxygenation (VA-ECMO) for Status 1, percutaneous endovascular support devices for Status 2, intra-aortic balloon pump (IABP) for Status 2, high-dose/multiple inotropes for Status 3, and low-dose inotropes for Status 4. The proportion of candidates meeting the cardiogenic shock criteria by cardiac index was calculated for each group. Patients listed with VA-ECMO and percutaneous support devices were conservatively categorized as "in shock" owing to high rates of missing hemodynamic data. We then analyzed the ability of the shock criteria to predict candidate death or delisting using both unadjusted Kaplan-Meier survival functions and competing risks models (to provide adjusted differences in transplant-free waitlist survival).

The registrations of 19,924 adult heart-alone candidates were analyzed. The cardiogenic shock criteria would have applied to 1,330 candidates per year on average (40% of all candidates listed in 2010–2015). We identified an average of 630 candidates per year (19% of yearly listings) that would have had their Status level reduced by the cardiogenic shock criteria (Table 1 and Figure 2). Of candidates, 40% of IABP candidates (Status 2), 62% of high-dose/multiple inotropes candidates (Status 3), and 47% of low-dose inotropes candidates (Status 4) would be listed at a lower priority Status. Candidates receiving multiple inotropes had a higher cardiac index (mean 2.24 liters/min/m^2 vs 2.16 liters/min/m^2; $p = 0.018$) and were more likely to be ineligible by shock criteria for Status 3 than candidates receiving high-dose inotropes (74% vs 40%; $p < 0.001$).

The presence of the shock criteria at listing did not affect the Kaplan-Meier estimated waitlist survival for any tested candidate group ($p > 0.18$ by log-rank test). We found a borderline significant difference in adjusted transplant-free survival based on shock criteria for IABP candidates (subhazard ratio for death delisting 1.50, 95% confidence interval 1.00–2.26) but no significant difference by the shock criteria for high-dose/multiple inotropes candidates and low-dose inotropes candidates ($p = 0.27$ and $p = 0.31$) (supplementary data, available in the online version of this article at www.jhltonline.org).

In this analysis of the SRTR database, we demonstrated that the cardiogenic shock criteria will likely reduce the priority for transplantation of >600 candidates a year—19% of all candidates listed in the United States. The major driver of disqualifications will likely be multiple inotropes and low-dose inotropes candidates. We also found that the presence of shock criteria at listing does not predict waitlist survival in any of the candidate groups subject to the shock requirement.

The consequences for the candidates who will not meet the shock criteria will be profound. Transplant programs will be forced either to list the candidates at substantially lower priority Status (presumably Status 6) or choose a support therapy that does not require the cardiogenic shock criteria. The therapies that are exempt from the shock criteria are typically surgically placed devices, such as a "Non-dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD)" for Status 2 listing.[1] We are concerned that programs will be incentivized to choose surgical ventricular assist device

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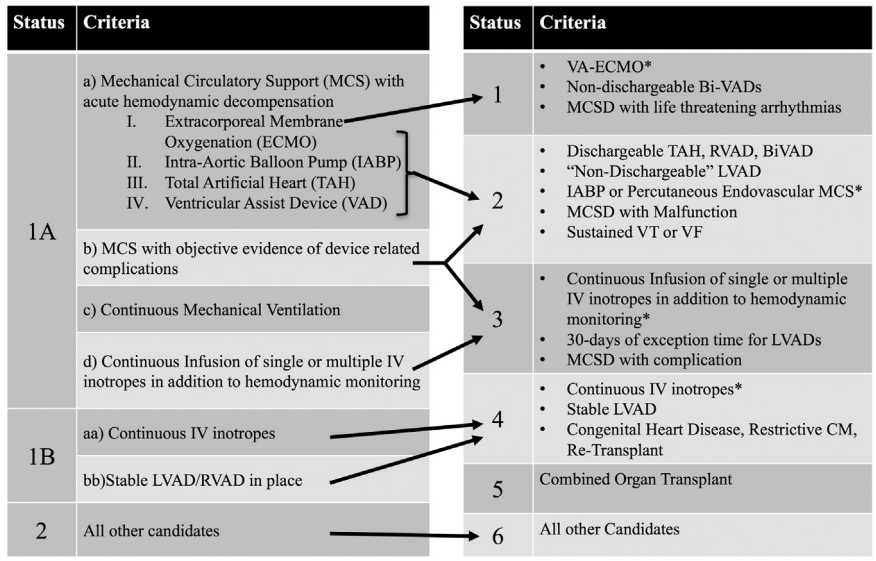

Figure 1 Current and future adult heart allocation. Schematic depiction of the shift from the current adult heart allocation system to the modified system. *Cardiogenic shock requirement applies. (Constructed with permission directly from the policy details in Organ Procurement and Transplantation Network.[1]).

support options over percutaneous or inotropic support strategies to circumvent the cardiogenic shock criteria and permit listing at higher priority Statuses.

The results of our waitlist survival analysis are consistent with previous work that demonstrated that mean pulmonary capillary wedge pressure, not cardiac index, is the important hemodynamic explanatory variable for predicting waitlist survival in heart transplant candidates.[3] Perhaps this is due to the unreliability of clinically obtained cardiac output measurements compared with gold standard measurements.[4,5] The lack of a significant transplant-free survival difference between candidates with and without the shock criteria also has important policy implications. If the intention of the policy is to prioritize candidates with a higher chance of

Table 1 Potential Impact of Shock Criteria

	VA-ECMO	Percutaneous endovascular support device	IABP	High-dose single inotrope	Multiple inotropes	Low-dose inotropes
Average yearly listings subject to shock requirement, *n*	40	4	118	119	190	862
Potential Status (new system)	1	2	2	3	3	4
Hemodynamics available, *n* (%)	23 (56)	3 (79)	109 (92)	102 (86)	175 (92)	830 (96)
Ineligible by shock criteria, *n* (%)	—[a]	—[a]	**47 (40)**	**48 (40)**	**141 (74)**	**393 (47)**
Disqualified by high cardiac index, *n* (%)[b]	—	—	47 (40)	45 (37)	55 (29)	393 (47)
Disqualified by low inotrope dose, *n* (%)[d]	—	—	N/A	2 (2)	29 (15)	—[c]
Disqualified by both high cardiac index and low inotrope dose, *n* (%)	—	—	N/A	1 (1)	57 (30)	—[c]
Cardiac index >3.0 liters/min/m^2, *n* (%)	—	—	8 (7)	26 (22)	34 (18)	64 (8)

IABP, intra-aortic balloon pump; N/A, not applicable; VA-ECMO, venoarterial extracorporeal membrane oxygenation.
Average number of candidates per year displayed for 2010–2015, rounded to nearest whole candidate. Percentages are by qualifying therapy group. **Bolded** candidates were candidates who would have been rendered ineligible by cardiogenic shock criteria. Candidates receiving high-dose inotropes and candidates receiving multiple inotropes can be disqualified by either high cardiac index or low inotrope dose.

[a]Disqualifications not calculated for VA-ECMO and percutaneous endovascular support devices owing to lack of hemodynamic data before mechanical circulatory support.

[b]Maximum cardiac index is defined as 1.8 liters/min/m^2 for candidates without inotropic support or 2.2 liters/min/m^2 for candidates with inotropic support.

[c]Candidates receiving low-dose inotropes can also be disqualified by low inotrope dose; however, inotrope dose data were unavailable for this group.

[d]Minimum inotrope requirements are (1) 1 high-dose intravenous inotrope (dobutamine ≥7.5 μg/kg/min or milrinone ≥0.50 μg/kg/min) or (2) at least 2 intravenous inotropes (dobutamine ≥3 μg/kg/min, milrinone ≥0.25 μg/kg/min, or dopamine ≥3 μg/kg/min).