1-13-2022

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Recommended Citation
Defilippis EM, Psotka MA, Khazanie P, Cowger J, and Cogswell R. Exploring Physician Perceptions of the 2018 United States Heart Transplant Allocation System. J Card Fail 2022.

Journal of Cardiac Failure Vol. 00 No. 00 2021

Brief Report

Exploring Physician Perceptions of the 2018 United States Heart Transplant Allocation System

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ABSTRACT

Background: After the implementation of the 2018 US heart transplant allocation system, the experience and perceptions of heart transplant clinicians have not been well-cataloged.
Methods and Results: This web-based survey of both heart failure cardiologists and surgeons examined physician perspectives about the policy changes and whether the system is meeting its intended goals. The majority of participants (94%, $n = 113$) responded that the 2018 heart allocation system requires modification. Eighty-four percent reported using more temporary mechanical circulatory support to achieve higher status and 86% were concerned about the change in physician behavior and practices under the new system.
Conclusions: Suggestions for possible improvement included higher status for patients on durable left ventricular assist device support, changes to criteria for status 2, modification of status exceptions, and advocacy for a heart allocation score. (*J Cardiac Fail 2021;00:1–5*)
Key Words: Heart transplantation, organ allocation, mechanical circulatory support.

The US advanced heart failure and transplant community has witnessed a dramatic change in practice since the new heart transplant (HT) organ allocation system went into effect on October 18, 2018. The primary goal was to better stratify patients by medical urgency and lower waitlist mortality in an effort to distribute organs to the sickest patients.[1,2] After its implementation, wait times have shortened for patients at the highest statuses but at the expense of substantial increases in the use of temporary mechanical circulatory support (MCS).[3,4] Additionally, because patients supported by left ventricular assist devices (LVAD) do not reach the highest status tiers without life-threatening complications, the use of durable LVADs as a bridge to transplantation has decreased substantially.[5] The novel coronavirus 2019 pandemic has impacted the ability of physicians to engage in discourse about the new allocation system. At present, the opinions of HT clinicians have not been well-described, including the extent to which the system change has met its intended goals. The purpose of this survey was to study HT cardiologists' and surgeons' opinions regarding the current HT allocation system.

Methods

The University of Minnesota Institutional Review Board reviewed and approved this study. We conducted a confidential, anonymous, voluntary, cross-sectional, electronic, web-based survey of HT cardiologists and surgeons between September 5 and 17, 2021. The survey was developed after a review of

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Manuscript received November 15, 2021; revised manuscript received November 21, 2021; revised manuscript accepted November 22, 2021.

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1071-9164/$ - see front matter

https://doi.org/10.1016/j.cardfail.2021.11.027

Table 1. Survey Questions with Multiple Choice Responses

Survey Questions	Responses						
I am a . . .	Heart failure surgeon 16 (13.3%)	Heart failure cardiologist 104 (86.7%)					
How many years have you been in practice?	<1 12 (10%)	1–3 15 (12.5%)	3–5 18 (15%)	5–10 36 (30%)	>10 39 (32.5%)		
I believe the allocation system for heart transplant instituted in 2018 (new system) requires modification.	Strongly agree 35 (29.2%)	Agree 48 (40%)	Somewhat agree 30 (25%)	Neither 4 (3.3%)	Somewhat disagree 1 (0.8%)	Disagree 2 (1.8%)	Strongly disagree 0 (0%)
I believe the new allocation system has resulted in harm for my patients through the overuse of temporary mechanical circulatory support.	Strongly agree 22 (18.3%)	Agree 40 (33.3%)	Somewhat agree 23 (19.2%)	Neither 12 (10%)	Somewhat disagree 13 (10.8%)	Disagree 7 (5.8%)	Strongly disagree 3 (2.5%)
My team is utilizing more temporary support than before the allocation system change to achieve a higher allocation status.	Strongly agree 40 (33.3%)	Agree 45 (37.5%)	Somewhat agree 16 (13.3%)	Neither 5 (4.2%)	Somewhat disagree 4 (3.3%)	Disagree 8 (6.7%)	Strongly disagree 2 (1.7%)
If there was a more reliable pathway for LVAD patients to receive a transplant, I would be more willing to place an LVAD as a bridge therapy.	Strongly agree 40 (33.3%)	Agree 45 (37.5%)	Somewhat agree 16 (13.3%)	Neither 11 (9.2%)	Somewhat disagree 6 (5.0%)	Disagree 1 (0.8%)	Strongly disagree 1 (0.8%)
I am concerned about the pattern of change in physician behavior and practices to achieve transplant under the new allocation system.	Strongly agree 37 (30.8%)	Agree 42 (35%)	Somewhat agree 24 (20%)	Neither 9 (7.5%)	Somewhat disagree 6 (5%)	Disagree 2 (1.7%)	Strongly disagree 0 (0%)
What percent increase in mortality is acceptable to you (compared to the prior era) in order to allow a pathway for the sickest patients to achieve a heart transplant more quickly?	0 41 (34.2%)	10% 69 (57.5%)	20% 5 (4.2%)	30% 2 (1.7%)	40% 0 (0%)	50% 3 (2.5%)	
I believe the new allocation system has stunted innovation and investment in durable mechanical circulatory support	Strongly agree 25 (20.8%)	Agree 29 (24.2%)	Somewhat agree 26 (21.7%)	Neither 17 (14.2%)	Somewhat disagree 11 (9.2%)	Disagree 10 (8.3%)	Strongly disagree 2 (1.7%)
I believe the new allocation system has reduced disparities (racial, gender) in heart transplantation.	Strongly agree 5 (4.2%)	Agree 17 (14.2%)	Somewhat agree 0 (0%)	Neither 61 (50.8%)	Somewhat disagree 10 (8.3%)	Disagree 18 (15%)	Strongly disagree 9 (7.5%)
I believe the COVID-19 pandemic has negatively impacted the HF community's ability to self monitor during this early phase of the new allocation system	Strongly agree 15 (12.5%)	Agree 35 (29.2%)	Somewhat agree 23 (19.2%)	Neither 34 (28.3%)	Somewhat disagree 6 (5%)	Disagree 6 (5%)	Strongly disagree 1 (0.8%)
How would you modify the current allocation system?			Free text response				

the published literature and subsequent semistructured focused discussions regarding item generation and reduction by HT clinicians, then pilot tested at the authors' institutions. Twitter was used to recruit survey participants. The final number of providers who had access to the survey for completion is not known. Participants accessed the survey using a web link and software to prohibit respondents from filling out multiple surveys from the same device. No login information was required to access the survey. Participants were able to forward the survey invitation. The survey contained 2 demographic questions (surgeon or cardiologist, years of practice), 9 statements about the new allocation system (7-point Likert scale from strongly agree through strongly disagree), and 1 free text question. No questions were mandatory. The complete 12-question survey is displayed in Table 1. Free-text responses were categorized thematically and summarized manually by E.M.D and R.C. Preliminary results were presented at the 2021 Heart Failure Society of American Annual Scientific Meeting.

Table 2. Suggestions to Improve the Current Allocation System ($n = 64$)

Theme*	*n* (%)	Sample Comments
Improve pathway to transplant for LVAD patients	28 (44)	"Allow VAD patients without complications to be permanent status 3 equivalent to inotropes plus PA line." "Patients with durable devices should not be penalized for 'clinical stability,' these are the best transplant candidates." "Not making LVAD patients have a life-threatening complication before they can get a transplant." "In recognition of the cumulative morbidity and mortality of durable VAD support, perhaps being status 4 longer than a certain period (say 3 years) would then qualify a patient to move to status 3 (or sooner for earlier generation devices like HM2 and HVAD)." "Allow increased flexibility/discretionary time for durable LVAD patients, particularly those with non-life-threatening but QOL-limiting complications of MCS." "Give higher allocation status to durable LVADs, particularly those implanted prior to the allocation change."
Modify status 2	18 (28)	"Make criteria for mechanical support stricter to require failure of inotropes." "Take away award for placement of temporary MCS and award patients who demonstrate the need. I do believe the new system awards placement of MCS when perhaps patient could similarly be supported by dual inotropes." "Restrict temporary MCS to sick patients with a one-week window and bail-out to VADs (combine status 1-2 for ECMO and Impella, remove IABP from devices allowed for status 2)" "Create further subdivision in status 2. Remove IABP as the major criteria for status 2." "IABP should be a status 3 and Impella $>$ 4L/min a status 2." "IABP needs to be policed better. The number of IABPs being placed to elevate status on patients on low-dose inotropes is ridiculous." "More emphasis on clinical status of the patient, rather than the treatment used."
Allocation Score	10 (16)	"LVAD time modeled and points for Black race." "Continuous score (ie, heartscore) modeled on expected gain in QALYs with versus without transplant with stratified results based on whether LVAD candidate." "Blood group adjustment to reduce harm of Group O." "Allow prioritization of sensitized patients (mostly women)." "Make it fair. . .sick patients with infiltrative cardiomyopathies, HOCM do not have a way out to higher listing than others." "There needs to be status priority adjustment for highly sensitized patients as well as for those who do not have LVAD option (severe RV failure, congenital, etc) as the number of transplants done at status 4−6 drops."
Regulate Exceptions	6 (9)	"Largest problem with current system is actually the utilization of exception requests and the almost universal acceptance of these requests." "Increasing need for exception letters demonstrates the gaps in current system. Would suggest study of exceptions sought and reasons for apply for exception (physiology, ie, are we ignoring a specific phenotype like ARVC versus SBP missed cutoff by 2 points)." "Need to have more restrictions on exemptions" "Reduce requirements for exceptions. . .that have become the norm." "Stricter regional review board oversight on status exemption requests may also be necessarily to limit 'creep' of the statuses into patients for whom they were not designed."
Other	6 (9)	"I would not allow for transplant off ECMO. I would place a much more stringent limitation on duration of temporary mechanical support (eg, 2 weeks)." "Despite the hope that the new system would decrease geographic inequities, I feel that our experience [. . .] equates to a worsening of regional disparities." "Change distance allocation to allow for a system that incorporates acuity of patient and distance of donor together".

*Respondents could be counted more than once if they suggested multiple themes. ARVC, arrhythmogenic right ventricular cardiomyopathy; ECMO, extracorporeal membrane oxygenation; HOCM, hypertrophic cardiomyopathy; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; MCS, mechanical circulatory support; PA, pulmonary artery; RV, right verntricular; QOL, Quality of life; SBP, systolic blood pressure; VAD, ventricular assist device;

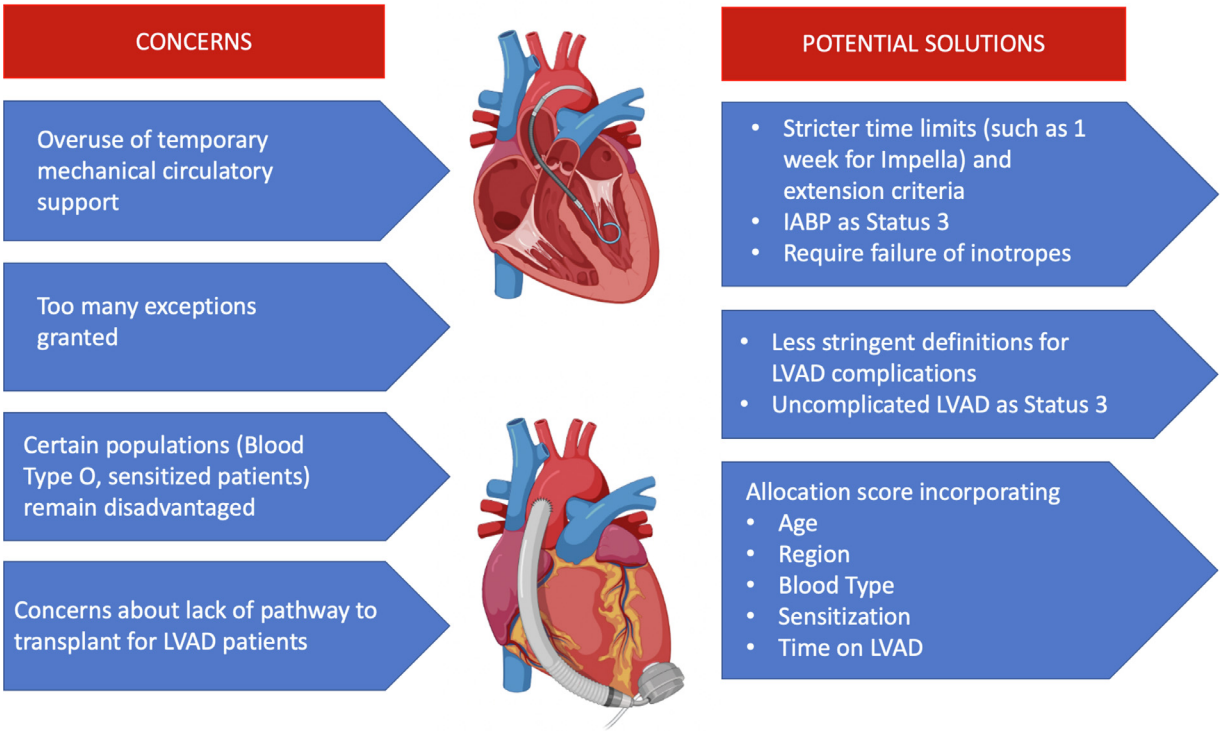

Fig. 1. Physician opinions about the 2018 heart transplant allocation system. Major concerns regarding the 2018 allocation system are depicted and potential solutions suggested. AIBP, intra-aortic balloon pump; LVAD, left ventricular assist device.

Results

There were 120 respondents, the majority of whom (87%, $n = 104$) were HT cardiologists. Thirty-two percent of the survey participants had been in practice for more than 10 years, 30.0% in practice for 5−10 years, and the remainder had been in practice for fewer than 5 years. The summary data for each response are displayed in Table 1. The majority of participants (94%, $n = 113$) responded that the new heart allocation system requires modification and 84% ($n = 101$) reported an increase in their institution's use of temporary MCS. Eighty-five percent ($n = 103$) were concerned about the pattern in physician behaviors and practices to achieve transplant under the new allocation system. Seventy percent ($n = 85$) believe the new allocation system could harm patients through the overuse of temporary MCS.

Eighty-four percent of respondents ($n = 101$) agreed that they would be more willing to place an LVAD as bridge therapy if there was a more reliable pathway for LVAD patients to be transplanted. When asked whether the new allocation system has decreased racial and gender disparities within HT, the majority neither agreed nor disagreed (51%, $n = 61$). When asked what percent increase in mortality is acceptable (compared with the prior allocation era) to allow a pathway for the sickest patients to achieve HT quicker, the majority of respondents (92%, $n = 110$) chose the lowest risk categories (0%−10 %).

Free-text substantive suggestions for the allocation system were completed by 66 participants (55%). Among the free-text answers, 1 participant stated that more time was needed to assess the current allocation system impact and another felt that temporary MCS was justified based on poor performance of LVADs. Suggestions for modification ($n = 64$) are outlined and sample comments are provided (Table 2). These included advocating for an easier pathway to transplant for LVAD patients (44%, $n = 28$), modifying the current status 2 (28%, $n = 18$), and using a heart allocation score (16%, $n = 10$). Regulating exceptions more closely was suggested by 9% ($n = 6$) of respondents. With respect to a potential allocation score, accounting for LVAD time, race, sensitization, and blood group O were all suggested.

Conclusions

This sample of advanced heart failure cardiologists and surgeons believe revisions are needed to the 2018 HT allocation system. The increasing use of exceptions, temporary MCS, and highest tier statuses to facilitate HT may be a cyclical problem. As more programs escalate by exception or temporary MCS use to higher listing statuses, higher status

listings are required for HT. Physicians use more temporary MCS under the current system and they are concerned this increases the risk for patient harm. The lack of a more rapid pathway to transplant for patients on LVAD support may also contribute to riskier MCS use, as physicians balance the safety of longer temporary MCS support with avoidance of a long-term LVAD. In addition, disparities may be perpetuated through differences in the use of temporary and durable MCS between centers and patient populations, particularly disenfranchised patients. It remains unclear how the 2018 allocation system may impact racial and gender disparities and further dedicated analyses are required to assess these issues. Such analyses may inform the eventual construction of an equitable heart allocation score.

These survey data can help to inform ongoing iterations of the HT allocation system. Although plans exist to begin modeling a heart allocation score in 2023, building this model, allowing for public comment, and implementing it will take time. We hope to foster a dialogue within the community about whether modifications within the existing system could be accomplished more quickly. Examples might include allowing higher listing status for patients with LVADs based on complications or time on LVAD support, or modifying status 2 to exclude IABP use (Fig. 1). Although an argument could be made to allow more time to determine whether the current trends will be sustained, the physician community sampled felt that modifications are needed to improve the equitable distribution of organs.

This study has limitations. Because participants were recruited through social medial platforms and snowball sampling, there was a selection bias. Such respondents may have been motivated to complete the survey if they disapproved of the current policy. Second, the sample size is small. Third, we could not calculate a response rate for this survey owing to snowball sampling and the lack of a denominator of eligible participants. Fourth, demographic information with respect to the physicians including age, sex, race, ethnicity, program size, and geography were not collected. However, despite these limitations, this survey helps in the ongoing re-evaluation of the policy change within the transplant community to develop durable improvements to the current allocation system for the benefit of all patients awaiting HT.

Conflict of Interest Statement

Ersilia M. DeFilippis: Nothing to disclose

Mitchell Psotka: Nothing to disclose.

Prateeti Khazanie: NIH/NHLBI K23 and NIH Ethics supplement award

Jennifer Cowger: Abbott- Advisory Board, speaker; Medtronic- Consultant, National PI, speaker; Zoll- speaker for fellow's conferences; Endotronix- unpaid steering committee member; Procyrion- Advisory board for Aortix device (stock options)

Rebecca Cogswell: Abbott Lab: HeatMate 3 Advisory Board, Medtronic: Heart Failure Advisory Board, Husband's employment

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