# The Heart Transplant Waiting List and the Interplay of Policy and Practice

## In Search of Fairness

See Article by Parker et al

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The national heart allograft allocation algorithm established by the Organ Procurement and Transplantation Network has undergone several major changes over the years. The main goals of these policy modifications have been to respond to the evolving treatment options for advanced heart failure patients, minimize the risk of death on the waiting list, and maximize the benefit of transplant.[1] An aspirational goal has also been to achieve as much uniformity as possible in the practical application of the allocation algorithm.

Every modification of the allocation policy in the past has been met with a good dose of anxiety in anticipation of what the implemented change will mean. Will the benefits to transplant candidates predicted by the statistical modeling of waiting list events be realized? Will the change affect the required level of staffing or the established process logistics of organizations participating in donation, procurement, and transplantation? Will the change alter transplant volumes at one's transplant center? Yet, the more contentious aspect has typically been the issue of uniform application of the policy from one transplant program to another and from patient to patient—a subject matter that can be best characterized as fairness.

In this issue of *Circulation: Heart Failure*, Parker et al[2] present their evaluation of one aspect of the fairness of the current heart allocation in the United States. They hypothesized that changes have taken place over time in the listing practices under the current Organ Procurement and Transplantation Network allocation policies at the level of individual patients. The authors noted that between 2000 and 2015, a rapidly increasing number of patients have been listed in the high-urgency status 1A, and they identified the 2 main patient groups responsible for this dramatic increase in 1A status listing: patients bridged with continuous-flow left ventricular assist devices, and patients without mechanical circulatory support on intravenous inotropic support. Interestingly, the authors also note that while there has been an increase in the number of patients listed in 1A status on multiple inotropes, the average dose of these inotropes has decreased over the years, while the patient hemodynamics in fact demonstrated improvement. The authors therefore conclude that these findings are evidence of overuse of inotropes intended to maximize status 1A listings by individual programs and that this expanding subgroup of patients competes for allografts with a sicker group of patients who are likely at a higher risk of mortality on the waiting list.

These findings undoubtedly demonstrate how policy can influence clinical practice at critical intersections of care. Yet, a conclusion that the full extent of the changes seen in the status 1A listings between 2000 and 2015 is a result of physicians taking advantage of a malleable listing criterion may be an oversimplification. Indeed, as the authors appropriately acknowledge, many additional events took place during the study period. In 2006, the Organ Procurement and Transplantation Network



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allocation rule change expanded the regional sharing of donor allografts, increasing transplant rates for the most ill patients, but also reducing the likelihood of transplant in patients at a more stable stage of their disease (ie, transplant of status 1B patients listed within the local organ procurement area became increasingly unlikely).[3,4] From 2008 onward, approval of continuous-flow left ventricular assist devices for clinical use in the bridge-to-transplant indication has fueled the use of this technology among patients with stage D heart failure and resulted in a very large proportion of candidates arriving at transplantation with a durable left ventricular assist device in place.[5] Importantly, an increasing number of patients would receive transplants in 1A exception status—and the United Network for Organ Sharing Regional Review Committees would overwhelmingly approve requests for these listing exceptions, thus affirming both the limitations of the current allocation algorithm to fully risk stratify patients within the main listing categories, and the aptitude of the transplant centers to identify the appropriate patients in need of expedited transplant.

The trends in the waiting list mortality are perhaps the strongest argument to suggest that the increase in 1A listings in patients on inotropic support has not been predominantly because of an arbitrary attempt to elevate the listing urgency among less ill patients. The implied overtreatment of transplant candidates should have presumably resulted in higher allocation rates to these less ill patients at the expense of more sick candidates, thus leading to an increase in the overall wait list mortality. Yet, this has not taken place. In fact, waiting list mortality has decreased over time in patients in all status listings. And, although the differences in the risk of mortality between patients listed as status 1A, 1B, and 2 have decreased, the risk of mortality has continued to closely correspond to the respective urgency of status 1A, 1B, and 2 listing as documented by the study authors and others (Figure).[6]

Regardless of the exact nature of the change in the distribution of patients listed for transplantation, the aggregation of a very large proportion of transplant candidates under the high-urgency status 1A category is undesirable. For one, these patients listed under the same urgency category have different risks of mortality; maybe even more importantly, this situation results in a reality where an expedited transplant is becoming more and more unlikely, as the median waiting times continue to rise along with the numbers of status 1A listed patients.[7]

Undoubtedly, the most attractive solution to the perceived lack of fairness in access to transplantation would be a granular allocation score. Yet, a reliable and accurate allocation score has to date remained beyond reach in clinical heart transplantation. This mainly because, at least in the short term, transplant is not the only possible treatment choice that will avert mortality. Intensive vasoactive support, temporary mechanical circulatory support, or durable mechanical circulatory support are all treatment modalities that may be considered for like patients.

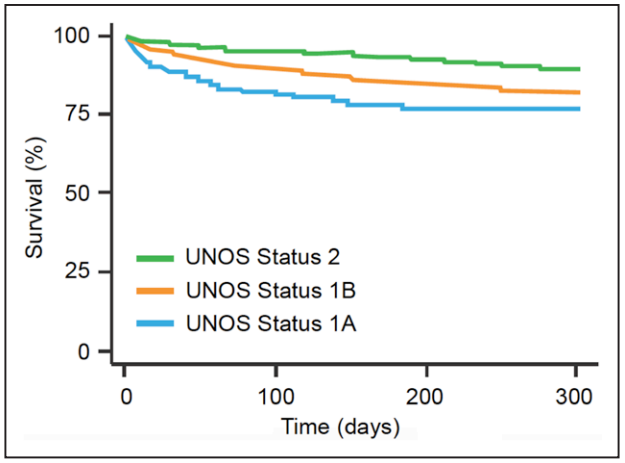


**Figure. Mortality on the waiting list among candidates without mechanical circulatory support listed between 2008 and 2011.**
Adapted from Wever-Pinzon et al.[6]

The report by Parker et al[2] provides important insights at the time of an anticipated change to the United Network for Organ Sharing allocation for heart allografts. It highlights the challenges of an allocation rule where therapy that a patient is receiving is used as a proxy for the urgency with which the patient should be listed/transplanted. The new allocation algorithm will still be subject to this limitation. Yet, in the key allocation categories, this will be mitigated by a requirement that the patients meet criteria for cardiogenic shock confirmed by invasive hemodynamic measurements. It is quite likely that treatment decisions for patients in need of transplantation will be influenced by how the respective intervening treatments will affect the chances of reaching transplant. The extent to which there will be a shift in clinical practice in response to the new allocation policy in selection of inotropic agents, temporary, and durable mechanical circulatory support cannot be easily predicted. It will certainly be important to carefully monitor events on the waiting list and post-transplant outcomes. Because some effects may turn out to be different than expected, willingness for iterative modification of the new rules may get the algorithm closer to the intended performance. It will also be of interest to explore whether the allocation change will impact the overall cost of care for stage D heart failure patients in need of advanced therapies.

The report by Parker et al[7] is a vibrant illustration of how allocation policy influences clinical decisions along the continuum of advanced heart failure therapies. Although the process of designing a revised allocation protocol is arduous and its implementation disruptive, the data presented validate the concept that these changes should be periodically pursued to maintain

fairness—equitable access to transplant balanced with maximizing its benefit.

## DISCLOSURES

Dr Stehlik has received research support from Abbott, Inc, and has served as consultant for Medtronic, Inc. The other author reports no conflicts.

## AFFILIATION

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## FOOTNOTES

*Circ Heart Fail* is available at http://circheartfailure.ahajournals.org.

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