Heart Allocation in the United States
Intended and Unintended Consequences

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The consequences of our actions are so complicated, so diverse, that predicting the future is a very difficult business indeed.
—J.K. Rowling, British Novelist (1965–present)

Nearly 20 years ago, clinical leaders in the field of heart transplantation met in Bethesda, Maryland, to address the growing disconnect between the numbers of patients with end-stage heart failure who were listed for cardiac transplant and those who actually received transplants.1 As stated by Dr Norman Shumway in his keynote address to the conference, “The principle issue that stands before us is the donor problem.” The severity of the crisis at the time was reflected in the fact that more patients were listed on any given date than underwent transplantation in the previous year. In an effort to ease the supply-demand mismatch, conference leaders developed objective criteria for candidate listing and prioritization, suggested new strategies to improve survival on the waiting list, and broadened donor selection. Despite these initiatives as well as the intensification of efforts toward public education, the actual number of transplants leveled off and has remained flat for more than a decade.2 Prioritization on the waiting list, however, has continued to evolve. In 1989, a simplified algorithm was implemented with 2 categories for medical urgency, and in 1999, a 3-tiered system (status 1A, 1B, and 2) was approved to address perceptions of unfairness in heart allocation. Most recently, the US allocation system was modified in 2006 to allow broader regional sharing of donor hearts to status 1A and 1B patients before allocating organs to local status 2 patients (Table).3 The primary objective of this algorithm change was to decrease wait-list mortality without effecting a change in posttransplant mortality.

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National Trends and the Intended Consequences of Allocation Change

Over the past decade, there has been a slow, but steady increase in the percentage of patients listed as status 1A and 1B and a decline in status 2 patients (Figure 1A).2 There are 2 major reasons given for these trends, including the increased use of mechanical circulatory support as a bridge to transplant4 and the tendency of programs to wait until patients deteriorate clinically before listing. This latter practice may be based on recent data showing similar long-term survival between patients receiving transplants as status 2 and those with advanced heart failure receiving optimal medical management.5 Furthermore, with the evolution of mechanical circulatory support, there has been increased attention focused on the posttransplant outcomes of bridged patients. In an initial report using Organ Procurement and Transplantation Network (OPTN) data collected between 1995 and 2004, intracorporeal ventricular assist devices (VADs) were associated with an increased hazard of both early (within 6 months) and late (beyond 5 years) mortality.6 However, these data were based primarily on first-generation, pulsatile-flow VADs. More recent data from both national7 and international8 registries show similar posttransplant outcomes between patients on continuous-flow VADs and patients not on VADs.

Against this background, Singh et al,9 in this issue of Circulation: Heart Failure, hypothesized that the risk of death while on the waiting list has decreased following the 2006 algorithm change. Using adult OPTN data from 2004 to 2009 (excluding retransplants and multiorgan transplants), they compared the overall and risk-adjusted wait-list mortality and early posttransplant mortality before and after implementation of the new allocation system. The analysis included 4503 patients in era 1 (2004–2006) compared to 7361 patients in era 2 (2006–2009). Importantly, complete data were available on age, sex, race/ethnicity, cardiac diagnosis, blood type, hemodynamic support, and United Network of Organ Sharing (UNOS) listing status as well as on dates of listing, transplant, death, and removal from the waiting list.

Following the algorithm change, listed patients were slightly older and heavier and more likely to be black and have type 2 diabetes and an implantable cardioverter-defibrillator (ICD). As anticipated, a greater proportion of patients in era 2 were listed as status 1A or 1B (57% versus 50%) and bridged with mechanical circulatory support, especially continuous-flow VADs. Despite this higher-risk profile, the wait-list mortality for status 1A and 1B patients decreased significantly by 17%, and in multivariable analyses, the use of continuous-flow VADs and ICDs predicted lower wait-list mortality. In a sensitivity analysis, decreased risk of wait-list mortality was also observed.
in patients not on VADs (hazard ratio, 0.77). Importantly, the 2006 algorithm change was associated with no change in hospital length of stay or mortality or 1-year posttransplant mortality, despite longer median waiting times (63 versus 55 days), decreased use of local donors (52% versus 62%), greater transport distance (125 versus 89 miles), and increased ischemic times.

The data by Singh et al9 are remarkable in their clarity and consistency, but what do they really tell us about the effect of the new allocation policy? As noted here, important trends toward increased wait-list status and decline in wait-list mortality have been observed for 10 years now (Figure 1).2 These data would suggest that the improved wait-list survival rates observed by Singh et al are coincidental with the 2006 change in heart allocation and due to other factors. Advances in the care of patients with end-stage heart disease, evolution of mechanical circulatory support, and more-careful attention to delisting marginal patients have all likely contributed to improved wait-list outcomes and due to other factors. Advances in the care of patients with end-stage heart disease, evolution of mechanical circulatory support, and more-careful attention to delisting marginal patients have all likely contributed to improved wait-list outcomes despite a sicker cohort. However, these advantages may not be generalized to all patients. In the current analysis, decline in wait-list mortality was observed only in white candidates (P=0.04 for interaction of white versus nonwhite) (Figure 3 in Singh et al). We have also observed that longer-term survival posttransplant has improved in white recipients but not in black or Hispanic recipients, resulting in a more marked disparity in outcomes in the current era.10 Risk factors not adjusted for in our prior analysis include differences in access to care, severity of illness at presentation, and rate of disease progression. Potential mechanisms responsible for worse outcomes in black patients include differences in biological factors (more hypertension, higher likelihood of human leukocyte antigen mismatch)11 and socioeconomic factors (lower socioeconomic status, less formal education).12

Black race has also been associated with worse outcomes following renal and liver transplant and attributed to a combination of biological and nonbiological factors.13,14 Going forward, specialized care, including individualized immunosuppression and quality improvement initiatives, may be critical to achieving similar outcomes and reducing healthcare disparities in organ transplantation.

### Unintended Consequences of Allocation Change

One of the unique aspects of transplant care in the United States is significant variability in listing strategies and waiting times among UNOS regions.15 Although the data of Singh et al9 suggest national progress toward improving wait-list outcomes, other published data have raised concerns about unintended regional consequences of allocation change. In an initial effort to look at the early effects of the 2006 algorithm, Nativi et al3 analyzed data from 4 Utah centers in UNOS region 5 and noted some concerning trends. As in the current report, there were significant increases in the percentage of status 1A and 1B patients receiving transplants (76% versus 44%) and bridged to transplant with VADs (31% versus 17%) after 2006. However, these investigators observed no change in wait-list or posttransplant mortality and increases in median waiting time, graft ischemic time, and donor procurement costs, the latter because of the increased number of imports and longer travel distances.

Even within a region, wait-list times, use of imports, and outcomes may vary. In a 6-month snapshot of UNOS region 1 data, we observed significant differences between

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**Table. Initial Sequence of Adult Heart Allocation**

<table>
<thead>
<tr>
<th>1999–2006</th>
<th>2006–Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local</td>
<td>Local</td>
</tr>
<tr>
<td>1. Status 1A candidates</td>
<td>1. Status 1A candidates</td>
</tr>
<tr>
<td>2. Status 1B candidates</td>
<td>2. Status 1B candidates</td>
</tr>
<tr>
<td>3. Status 2 candidates</td>
<td>Zone A</td>
</tr>
<tr>
<td>Zone A</td>
<td>3. Status 1A candidates</td>
</tr>
<tr>
<td>4. Status 1A candidates</td>
<td>4. Status 1B candidates</td>
</tr>
<tr>
<td>5. Status 1B candidates</td>
<td>Local</td>
</tr>
<tr>
<td>5. Status 2 candidates</td>
<td></td>
</tr>
</tbody>
</table>

Adapted from Nativi et al.3 Zone A refers to all transplant centers within 500 nautical miles of the donor hospital.

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**Figure 1.**

centers and between time points in the ratio of status 1A to 1B patients between centers and between time points.

Emerging Issues and Future Prospects

On balance, advance heart disease physicians and healthcare extenders should be cautiously optimistic. Perioperative care and overall survival of heart transplant patients continue to improve. Although additional analyses are needed to demonstrate no detrimental effect of allocation change on longer-term outcomes, the evolution in VAD technology and emerging understanding of myocardial recovery and stem cell biology may obviate the need (or at least the urgency) for heart transplant. The REVIVE-IT (Randomized Evaluation of VAD Intervention before Inotropic Therapy) trial will determine the role of continuous-flow VADs in patients with stable moderate heart failure, whereas a small, but growing number of patients will be living at home on total artificial hearts. Additionally, novel organ preservation techniques may allow significant increase in travel distances without compromising donor heart function. Within this framework, the UNOS Thoracic Organ Committee will be challenged to rethink the allocation algorithm and should consider the use of severity of illness scores (eg, the lung allocation or model for end-stage liver disease scores) for better risk stratification. This will likely be more complex, however, as the indexes of disease severity in heart failure are more amenable to the effects of therapy, which can then be modified to achieve shorter waiting times. In addition, heart allocation simulation models should be redesigned to account for changing demographics, indications for transplant, and comorbidities (eg, obesity, diabetes) as well as the stability of physician and patient preferences in the face of life-threatening illness.

As suggested by J.K. Rowling, predicting the consequences of policy change is a difficult business, indeed. Heart transplant leaders who gathered in Bethesda in 1992 understood the importance of forward thinking and outlined broad principles for improving both wait-list and posttransplant outcomes. As the field evolved, policymakers tried to redirect the donor algorithm to benefit sicker patients. Despite these efforts, the current system is flawed by perpetuating regional and center differences that threaten the principles of fairness and equity in donor allocation. Furthermore, racial and ethnic disparities in transplant care persist. It is the responsibility of current and future advanced heart disease leaders to maximize the intended, and limit the unintended, consequences of allocation policy.

Disclosures

None.

References


Key Words: Editorials • heart transplantation • heart-assist devices • heart failure • health policy • outcomes research
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Circ Heart Fail. 2012;5:140-143
doi: 10.1161/CIRCHEARTFAILURE.111.966135
Circulation: Heart Failure is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2012 American Heart Association, Inc. All rights reserved.
Print ISSN: 1941-3289. Online ISSN: 1941-3297

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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