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EDITORIAL COMMENT

Time for Change in United States Donor Heart Allocation Policy*

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In this issue of *JACC: Heart Failure*, Schulze et al. (1) report on the impact of the 2006 United Network for Organ Sharing (UNOS) donor heart allocation policy change on patients waiting for heart transplant and post-transplant patient outcomes in the United States. This policy change allocated donor hearts to the most sick patients (status 1A/1B) first locally, then to Zone A (500-mile radius from the donor hospital), then to Zone B (1,000-mile radius), with the goal to reduce waitlist mortality. Importantly, the authors demonstrated a reduction in waitlist and post-transplant mortalities while illustrating differences in regional waitlist time and mechanical circulatory support device (MCSD) use after the policy change. The authors also noted an overall increase in average waitlist times since the 2006 policy was implemented. The authors conclude that the 2006 policy change and the recent greater use of MCSDs both contributed to the reduction of waitlist and post-transplant mortalities. In addition, presumably due to the longer waitlist times, the use of MCSDs increased more dramatically in several regions. The authors raise concern that the longer waitlist time might result in more MCSD complications that could lead to worsening post-transplant outcome in the future.

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In the study by Schulze et al. (1), there is much emphasis on waitlist times and the heterogeneity of waitlist times and MCSD use among the different regions. Although it is true that average waitlist times in status 1A/1B patients significantly increased after the 2006 UNOS donor heart allocation policy change, is longer waitlist time truly an issue of whether waitlist mortality is reduced? Does 1 week or 2 truly make a difference in outcome? The authors suppose that it is the 2006 donor heart policy change and more MCSD use that accounts for the increase in waitlist times and heterogeneity among regions. However, this analysis fails to consider and accommodate for other possible reasons for these observed changes. For each UNOS region, data should include number of heart transplant programs in the region, number of MCSD programs in the region, population of the region, average number of donors/capita, and efficacy of the local organ procurement organization. Other factors include the aggressiveness of the transplant center to use marginal donor hearts, differences in donor management, and different philosophies about who to list and when to list for transplant. Only when these factors can be ascertained, can there be more reliable analyses of regional differences.

It seems clear that the increase in MCSD placement is having an impact on the management of patients on the heart transplant wait list. The emergence of MCSDs in addition to advances in heart failure medical therapy has had the most impact in lowering waitlist mortality. The early use of MCSDs (before 2006) did not have satisfactory survival as seen in the REMATCH (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) randomized trial of MCSD versus medical therapy (2). In this study (2001), survival at 2 years was 8% for the medical therapy group and 23% for the MCSD group. Over the course of several years, particularly with the advent of continuous flow devices (after 2006), survival for these patients has improved dramatically (3,4). This raises the issue of how these patients should be prioritized on the waiting list.

The Interagency Registry for Mechanically Assisted Circulatory Support reports a 70% significant adverse event rate at 1 year post-implantation including complications such as thrombus formation, bleeding, driveline infection, and device malfunction. These patients with device-related complications are reported to have outcomes analogous to Status 1B patients (1). Because MCSD complication risk is high and no one can predict who will have a significant adverse event on MCSD, these patients (including stable MCSD patients) should have priority on the waitlist. Patients with a total artificial heart (TAH) should also merit priority listing. These patients are also at risk for post-device complications with increased risk of morbidity and mortality (5). There is no native diseased heart to provide backup in a case of TAH malfunction, unlike with MCSD patients. These patients thus warrant listing at a higher allocation status.

If waitlist and post-transplant mortalities have been reduced, then what other issues are important? Aside from the MCSD patients, there are several disadvantaged groups awaiting heart transplant that merit discussion. One subgroup at risk are those patients with restrictive cardiomyopathy such as hypertrophic cardiomyopathy and amyloid patients. These patients might not have systolic dysfunction and, in general, do not benefit from inotropic therapy or from left ventricular assist devices, which are currently criteria for status 1A listing. These patients usually have biventricular heart failure and would require a TAH for

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support if needed. The highly sensitized patient is another disadvantaged subgroup. These patients have been noted to have a longer waitlist time due to a smaller donor pool, as many potential donors are not compatible (6). In Canada, highly sensitized patients have been given priority in one of the highest categories (7). This priority listing does not take into account challenges in antibody detection technology or standardization of how an unacceptable antigen is defined. Despite these controversies, it would be to the advantage of the patient and the listing transplant center to not have a higher calculated panel reactive antibody level, because this would reduce the potential donor pool for that patient. A system whereby these highly sensitized patients might warrant a higher listing status should be pursued. Finally, adult patients with congenital heart disease also face problems in qualifying for status 1A listing. These patients have unusual anatomy, which might preclude invasive hemodynamic monitoring and preclude the use of mechanical assist devices.

For these subgroups of disadvantaged patients, policy change to the current donor heart allocation scheme is needed. The authors point out several potential U.S. donor heart allocation policy changes. This all assumes that there is room for improvement in reduction for mortality both pre- and post-transplant as well as to better serve the disadvantaged populations as described. There must be balance for treating the sickest patients, because these patients have the highest waitlist mortality (i.e., patients on ventilator treatment and extracorporeal membrane oxygenation treatment) and often have compromised post-transplant survival.

To serve the sickest patients, I believe that donor hearts should be allocated by geography deleting local allocation. This would mean the donor hearts would be allocated to status 1A then 1B patients in Zones A, B, and C (1,500 mile radius). Status 2 patients would then follow in the order of the geographic zones. In the short term, the most practical donor heart allocation policy change might be to increase the number of tiers, which would accommodate MCSD patients so that they have proper higher priority. The same can occur for other disadvantaged patients, including restrictive cardiomyopathy, the highly sensitized patients, and congenital heart disease patients. The exact inclusion criteria for each tier will need to be discussed. The disadvantage for this proposal is that there is no priority given within each tier so that sicker patients are transplanted first. Finally, like the lung allocation score, a heart allocation score should be pursued in the long term. One of the most vexing problems with the heart allocation score is that the variables used have not been validated. The MCSD field is rapidly changing, and therefore variables that might be important today might not be relevant in the future. Indeed, with these changing times, it would be difficult to establish a long-lasting heart allocation scoring system. However, it is imperative that as a community we begin the process of identifying, gathering, and analyzing data for the needed variables that could ultimately inform the calculation for a heart allocation score. Eventually, this might be the best alternative policy to ensure that the sickest patients would have the highest priority.

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