

seemed to have widened, based on the increase in median travel distance for the donor hearts.⁴ However, there were also some findings that do give one pause and are worth addressing. Of the 124 transplanting centers examined, a little less than half performed *fewer* transplantations after the new allocation guidelines were implemented. Although there seems to be a wider area of distribution for these donor hearts, that distance comes with a price—a statistically significant increase in ischemic time, which may in part explain why the 180-day post-transplant mortality was also greater for patients after the update to the guidelines. By continuing to transplant patients after the allocation changes, whether due to lack of resources, increased donor ischemic time, or other intangibles, have some of these centers flown too closely to the sun?

It is important, as the authors themselves note, that some of the data was acquired early after October 2018, and there may not have been a sufficient sample size to draw any firm conclusions about the updated allocation system. Changes made by the United Network for Organ Sharing result in more donor organs—but we would do well to remember that there may be some unintended negative consequences, as there were for the listed status 2 patients after the 1999 United Network for Organ Sharing change to the allocation scheme.⁵ What also, of the 56 programs whose transplant

volumes decreased after the change to the allocation system? Centralization of care may have some advantages but may also limit access to patients who are unable to travel. Myths are still told even thousands of years later because the lessons they impart are still relevant to us today. Let us continue to pursue changes to the allocation system, let us continue to maximize the hearts transplanted. We must continue to study the outcomes of the patients transplanted after the update and use the sturdy wings of knowledge to safely propel all transplant centers and our patients forward. Let us do better than Daedalus!

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Check for updates

Commentary: The ethics of donor allocation

Vivek Rao, MD, PhD

Cardiac transplantation involves major ethical dilemmas at all stages of the transplant process. In contrast to liver and kidney donors, an increasing proportion of whom are living-related, heart donors are primarily young individuals



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CENTRAL MESSAGE

All aspects of cardiac transplantation involve important ethical considerations. Changes to any of these aspects demand careful consideration and constant evaluation of their impact.

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Disclosures: The author reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

Received for publication Sept 21, 2020; revisions received Sept 21, 2020; accepted for publication Sept 23, 2020; available ahead of print Sept 28, 2020.

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J Thorac Cardiovasc Surg 2021;161:1849-51

0022-5223/\$36.00

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<http://dx.doi.org/10.1016/j.jtcvs.2020.09.088>

with irreversible brain death.¹ Families who consent to give this “gift of life” are reassured that organs from their loved ones are allocated in a fair and impartial manner to those in most need.

Historically, the presence of decompensated cardiogenic shock requiring inotropic or short-term mechanical circulatory support (MCS) identified those recipients at greatest risk of waiting list mortality. Despite their increased perioperative risk with transplantation, it was felt that urgent allocation to these patients was both ethical and in society’s best interest.² However, the introduction of reliable and durable MCS devices changed the landscape. Arguably, the introduction of continuous-flow left ventricular assist devices (LVADs) in the previous decade made the most impact on transplant programs.³ Faced with the desire to increase volumes while simultaneously reducing wait-list deaths and preserve “acceptable” surgical outcomes, more and more programs advocated for the use of implantable LVADs as a bridge to transplantation. Although no large randomized trial data exist, early reports with even earlier-generation pulsatile devices demonstrated that durable long-term mechanical support was superior to inotropic support in patients awaiting transplantation.⁴

Given these data, organ sharing networks in the United States and Canada awarded similar status to patients at home on a MCS device as those waiting in hospital on inotropic therapy. The logical reasoning was to encourage programs to implant LVADs in high-risk transplant candidates to transfer the surgical risk of transplantation to the time of LVAD implant. Considering that the scarce resource is the valuable human heart, this approach ensured that each transplanted heart had the optimal opportunity for long-term survival. While the use of extracorporeal life support (ECLS) and short-term VADs still provided heart transplant candidates with higher priority, the outcomes of transplant following durable support were superior compared with either of these technologies and most programs opted to “upgrade” short-term devices to durable systems to improve their institution’s transplant-related survival.

However, the remarkable success of patients supported by implantable devices also led many to question their privileged status on organ waiting lists. While the development of a device-related complication naturally led to an upgrade in urgency, many argued that stable VAD recipients should no longer receive preferential listing status.

Therefore, after considerable debate and controversy, the United Network for Organ Sharing (UNOS) in the United States enacted a policy change in October 2018. There is now a 6-tier allocation system with preference given to the sickest candidates on the waiting list. Early concern about the potential impact of this allocation change on clinical practice and subsequent survival following transplant was magnified by an early UNOS registry report that suggested poorer survival after the

allocation change despite a reduction in waiting times and waiting list mortality.⁵

In this issue of the *Journal*, Estep and colleagues⁶ have provided updated data suggesting that the enacted changes have resulted in the proposed benefits: namely, a reduction in waiting times and waiting list mortality, greater sharing of organs between procurement regions and similar 1-year post-transplant survival compared with the era immediately before the allocation change. These data are certainly encouraging; however, they may be a bit premature, as many programs (particularly smaller ones) may not have altered their management algorithms to account for the new policy. Indeed, this report includes observations that 50% of the programs performed fewer transplants after the allocation change. To date, there has not been an analysis of the impact of the allocation change on centers’ transplant activity stratified by their annual volume. It is entirely conceivable that larger transplant programs will always have an urgent patient on ECLS support who will supersede a patient on the waiting list at a smaller program. Furthermore, smaller programs may soon move to place their sicker patients on ECLS support to prevent this erosion of donors. If all programs in the United States conformed to a uniform management strategy, then logic dictates that the regional movement of organs will no longer occur. Rather, organs will be used locally by a program that has supported their patient with a short-term device. While the impact of this “management” change has not yet been reflected in 1-year survival, it is noteworthy that the authors document a 4-fold increase in the use of venoarterial extracorporeal membrane oxygenation or other short-term MCS devices. Again, as competition for donor organs “force” programs to use short-term MCS devices, it is likely that the regional redistribution seen in this study will no longer occur. Instead, we can likely predict longer waiting times for donor organs even for patients in the new status 1 tier. This will undoubtedly lead to inferior post-transplant survival as patients often deteriorate after prolonged short-term support in contrast to the improvement we see in most patients after institution of durable mechanical support.

Repeated analyses such as this report by Estep and colleagues will be needed to document the time-varying impact of the UNOS allocation change on post-transplant survival as programs across the United States adapt to serve their patients. It is important that from a societal perspective, the goal should be to optimize survival from the onset of listing and not just following transplant. The latter approach may give false optimism at the post-transplant survival in patients supported with short-term MCS devices while ignoring the proven mortality and morbidity risk with these devices compared with durable implants.

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Commentary: The only constant is change: Understanding the changes in the new heart allocation system

Ryan C. Knoper, MD, and Ranjit John, MD

The 2018 change in the United Network for Organ Sharing heart allocation system emphasizes balance through a 6-tiered, weighted system. This change was motivated by overcrowding at the highest acuity levels in the previous system and subsequent inequities in disadvantaged groups such as adult congenital heart disease and restrictive cardiomyopathy as well as potential recipients who were ineligible for ventricular assist devices (VADs).¹

Estep and colleagues² reviewed the current data and publications analyzing the influence of these 2018 changes. As with any change, it is important to observe and quantify the influence of those changes to determine whether they have had the desired effect and ensure that there are no major negative or unpredicted outcomes. They address the groups most influenced by those changes and offer guidance to



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CENTRAL MESSAGE

A change in UNOS heart allocation appears to be a step in the right direction. Further long-term and subgroup analysis remains necessary to ensure equal and fair allocation of a finite resource.

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Disclosures: Dr John is the recipient of a research grant from Abbott Medical and Medtronic. Dr Knoper reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

Received for publication Oct 1, 2020; revisions received Oct 1, 2020; accepted for publication Oct 2, 2020; available ahead of print Oct 27, 2020.

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J Thorac Cardiovasc Surg 2021;161:1851-2

0022-5223/\$36.00

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<http://dx.doi.org/10.1016/j.jtcvs.2020.10.006>

programs navigating novel management strategies to optimize patient outcomes.

Finding balance between allocation of organs to the sickest patients before they die while ensuring longevity in the post-transplant recipient is a challenge the weighted system is designed to overcome. The highest tier is reserved for the sickest recipients, with the highest expected waitlist mortality, whereas the lowest tier represents the reciprocal. Significant findings discovered in these early analyses show that donor hearts are traveling further, with longer ischemic times.³ Recipients also have shorter waitlist times but have worse hemodynamic status and increased use of temporary support