

# Changes in United States heart allocation: A community energized to improve policy

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## ABSTRACT

Donor heart allocation in the United States has not evolved in concert with changes in the characteristics of patients on the waiting list or evolution in technology. Data showing the growing population of patients with advanced heart failure coupled with the relatively fixed number of cardiac donors and regional access disparities motivated the United Network for Organ Sharing (UNOS) Thoracic Committee to reexamine candidate prioritization and broader organ sharing. The resultant proposed policy change stratifies patients in a more granular manner based primarily on wait-list mortality and is designed to expand the geographic boundaries to permit greater access to donor hearts for the most critically ill patients awaiting transplant. (J Thorac Cardiovasc Surg 2016; ■:1-3)



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## Central Message

The thoracic committee of the United Network for Organ Sharing has proposed changes to US heart allocation policy. The rationale for this revision and the current status of the policy are reviewed.

**Feature Editor's Note**—Recently, the Organ Procurement and Transplant Network and United Network for Organ Sharing thoracic organ transplantation committee has proposed changes to the current donor heart allocation policy to address inequities in donor heart allocation that have arisen from important changes in the contemporary practice of heart transplantation. These changes in contemporary medical practice have arisen largely from: (1) more frequent incorporation of mechanical circulatory support as a bridge to heart transplant in the listing paradigm and (2) greater variability in patient conditions leading to heart transplant that are not adequately characterized by the current allocation system and require exemption status to achieve priority. The most recent undertaking of modifying the donor heart allocation process in the United States has been arduous, reflecting the

complexities of patient care and differing priorities among transplant physicians and centers. The proposed tenets underlying the proposed donor heart allocation scheme are to give greater priority to patients more on the basis of physiologic metrics rather than on that of physician-directed treatments. Another important aspect of the proposed allocation policy will be to increase regional sharing by elimination of the organ procurement organization as a geographic unit to assign allocation. The future effects that the proposed changes in donor heart allocation will have on the practice of heart transplantation are unknown. Although no donor heart allocation process can be without limitations, the proposed changes to the process do attempt to address some of the most glaring inequities (eg, geographic sharing) and attempt to make the allocation process more granular with respect to assigning priority. Moving forward, more data on patient characteristics will likely be needed for a better understanding of patient risk while awaiting heart transplant, the better to inform future policy changes that address inequities in donor heart allocation.

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**Abbreviations and Acronyms**

|      |                                            |
|------|--------------------------------------------|
| OPTN | = Organ Procurement and Transplant Network |
| UNOS | = United Network for Organ Sharing         |
| VAD  | = ventricular assist device                |
| PRA  | = panel-reactive antibody                  |

The US government created the Organ Procurement and Transplant Network (OPTN) in 1984 to provide structure, operational efficiency and equitable access to donor organs across the country. The OPTN, operated by a contract with the US Health Resources and Services Administration, is held by the United Network for Organ Sharing (UNOS), a nonprofit organization headquartered in Richmond, Virginia. UNOS policies and regulations are governed by the National Organ Transplantation Act and the OPTN Final Rule. During the past several years, the Thoracic Organ Transplantation Committee of OPTN and UNOS has become increasingly aware that current US heart allocation policy is outdated relative to contemporary practice and does not embrace some of the OPTN Final Rule precepts. To address this situation, the committee began work to change heart candidate prioritization and allocation in the United States.

Throughout this redesign process, the committee reviewed longitudinal data demonstrating that heart transplant candidate demographics, comorbidities, and risk had evolved significantly since the last major revision of the US heart allocation policy. For example, the sickest candidates on the heart transplant waiting list (status 1A) have a 3-fold higher rate of death before transplant or waiting list removal for clinical deterioration than other listed candidates. Mechanical circulatory support used as a bridge to transplant and the associated complications have rapidly expanded during the last decade. Further, a myriad of ventricular assist device (VAD) complications lack uniform definitions and are treated similarly in policy, without acknowledging the variability in associated candidate risk. A large number of candidates are unaccounted for in contemporary policy language and require listing by exception. Perhaps the most glaring examples are those candidates with refractory ventricular arrhythmias, who currently do not fit in to any of the recognized listing categories. Finally, the committee did not believe that our current heart geographic sharing policies are aligned with the spirit of the OPTN Final Rule, which states that organs should be shared as broadly as is medically reasonable.

The primary goal of candidate reprioritization and broader sharing was to reduce waitlist mortality and delisting for clinical deterioration while ensuring that the changes did not negatively affect posttransplant survival. The Heart

Subcommittee used OPTN data and clinical experience to create a strawman to reprioritize candidates into 6 (as opposed to the current system of 3) medical urgency statuses. The committee also developed 4 separate alternatives for broader organ sharing and concluded that the scheme that shares hearts as far as 1000 miles for the sickest candidates on the heart transplant waiting list was medically reasonable and would provide the greatest opportunity for the most urgent candidates to receive transplants in an expedient manner. The reprioritization and broader sharing paradigms were then evaluated with a Thoracic Simulation Allocation Model performed by the Scientific Registry of Transplant Recipients. The combination of the proposed reprioritization and broader sharing rules will result in a new stratification system that separates patients in a graded manner from highest to lowest mortality risk and increase transplantation rates for the most critically ill patients without negatively affecting posttransplant survival.

The new proposed heart allocation policy was submitted for public comment in the spring of 2016 and received many constructive critiques and suggestions for improvement. The committee is working on revisions to the proposal on the basis of the public comment feedback.

Perhaps the most poignant theme expressed by the medical community and public was concern that the proposed high urgency statuses might influence practice changes, including the overuse of specific therapies. One potential solution to address this concern is to create a construct in which all high-priority status criteria are time limited, with automatic downgrading unless objective criteria demonstrate requalification for the high-priority status. The use of continuous mechanical ventilation was previously included as a high-priority criterion, but this will be removed in the new proposal on the basis of observations that this is not an accepted treatment for heart failure in adults and is likely to be collinear with other criteria that would allow a candidate to be listed at high priority.

Another important theme that came from public comment was that the new policy should acknowledge the poor prognosis associated with biventricular heart failure and the worse survival outcomes associated with its treatment relative to patients with isolated left ventricular failure. The committee is currently deliberating changes to policy language that reflect this important concept, with support device strategies used as a surrogate to reflect disease severity. Appropriate prioritization of candidates maintained on total artificial heart support was another important consideration, particularly if candidates are dismissed from the hospital. Currently, there are few data to guide the decision regarding whether hospitalized candidates with total artificial heart support should be listed in a more urgent status than those not in the hospital, but the consensus of the committee and the community

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