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

Joseph G. Rogers, MD

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;152:1484-6)

Joseph G. Rogers, MD

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.

See Editorial Commentary page 1487.

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.

Frank D. Pagani, MD

From the Division of Cardiology, Duke University, Durham, NC.
Received for publication June 24, 2016; revisions received July 11, 2016; accepted for publication July 12, 2016; available ahead of print Sept 29, 2016.
Address for reprints: Joseph G. Rogers, MD, Division of Cardiology, Box 3034 DUMC, Durham, NC 27710 (E-mail: Joseph.rogers@duke.edu).
0022-5223/\$36.00
Copyright © 2016 by The American Association for Thoracic Surgery
<http://dx.doi.org/10.1016/j.jtcvs.2016.07.077>

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

is that the technology is limited at present and there is no safety net for these patients in the event of device failure. As a result, candidates with total artificial heart support will remain as status 2 regardless of confinement to hospital.

Our contemporary understanding of the impact of VAD complications on transplant candidate risk is limited by a lack of uniform definitions in policy. The proposed revisions not only contain specific language describing VAD-related morbidities that qualify candidates at a higher priority but also acknowledges differential waiting list mortality according to the data available in the OPTN database. The committee is also considering other VAD issues, such as whether to maintain the 30-day discretionary time for patients who are stable with VAD support to be listed at a higher priority and criteria for demonstration of the ongoing need for intravenous balloon support or treatment with acute percutaneous endovascular cardiac support devices.

The committee has attempted to devise policy language that will guide candidate prioritization according to physiology rather than to physician treatment decisions. In this light, it proposes to use the American Heart Association definition of cardiogenic shock,¹ which includes a systolic blood pressure of less than 80 to 90 mm Hg, a cardiac index of 1.8 L/min/m² or less without inotropic or mechanical support or 2.2 L/min/m² or less with support, and demonstration of sufficient left-sided filling pressures (a pulmonary wedge pressure >15 mm Hg).

The committee deliberated the importance of prioritizing candidates with high levels of anti-human leukocyte antigen antibodies. Unfortunately, nearly 25% of programs do not submit unacceptable antigen data to the OPTN database, and among the programs that reported any unacceptable antigens, the calculated panel-reactive antibody (PRA) was 0 in 80% of candidates. It is unknown whether the negative reported PRAs in these candidates are accurate, or if centers are not entering PRA information to field more potential donor offers. The committee is committed to collection of more granular PRA data and other factors that will help inform the future revisions to heart allocation policy.

The final important theme that the committee will address in the new proposal pertains to broader sharing of donor hearts. Concern was expressed by the transplant community that extending procurement distance to 1000 miles for the most critically ill candidates would lengthen cold ischemic time, might disenfranchise local organ donation, and would have the potential to delay organ procurement and increase cost. The committee plans to move forward with a revised allocation scheme that shares hearts to 500 miles (rather than 1000) and will request additional modeling to examine the predicted impact of this change on waiting list and posttransplant mortality, transplant rates, and regional differences in net donor heart movement.

It is certain that the complexity and heterogeneity of heart transplant candidates, the distribution of the US populace, and the relative shortage of hearts suitable for transplant will preclude development of an allocation system that provides equitable access to all individuals awaiting cardiac transplants. We are obligated, however, to improve risk stratification and access for candidates in the United States. No new policy will account for changes in physician or center behavior, nor will it account for the willingness of individual centers to accept risk for the use of donor organs with higher-risk features. It is the belief of the OPTN and UNOS thoracic committee that the proposed allocation system changes represent an incremental but significant improvement relative to our current prioritization and organ allocation rules. A revised version of the policy that incorporates the public comments will be released again in the fall 2016 OPTN public comment cycle.

Conflict of Interest Statement

Author has nothing to disclose with regard to commercial support.

Reference

1. Reynolds HR, Hochman JS. Cardiogenic shock: current concepts and improving outcomes. *Circulation*. 2008;117:686-97.

Key Words: heart allocation, Organ Procurement and Transplant Network, United Network for Organ Sharing, heart transplantation, public policy