Potential Impact of the Proposed Revised UNOS Thoracic Organ Allocation System

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The current United States heart allocation system faces 2 main challenges: an evolving landscape of device therapy in advanced heart failure and a rapidly increasing transplant waiting list. The proposed new heart allocation system involves expansion of the 3 tiers and enables greater distinction between different types of mechanical circulatory support devices. In this review, we discuss how the proposed revision reconciles key concerns of the current system to create a more fair and equitable allocation of hearts in the United States.

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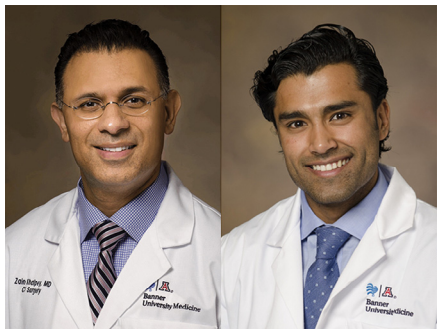

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Central Message

The proposed new United States heart allocation is an improvement on the current system, particularly in its attempt to address evolving device therapies for advanced heart failure. We anticipate improved waiting list mortality in tandem with maintaining adequate post-transplant outcomes.

INTRODUCTION

First performed in the United States in 1968, heart transplantation is now the most effective treatment for patients with advanced heart failure refractory to medical and surgical therapies and a median life expectancy of 10-15 years.[1] Five percent to 10% of the 2.5 million adults in the United States with heart failure with reduced ejection fraction would be candidates for heart transplantation.[2] The development of effective immunosuppressive therapies and antibiotics has contributed to a marked decrease in post-transplant mortality in this population.[1] The United Network for Organ Sharing (UNOS), acting through its role as the Organ Procurement and Transplantation Network (OPTN), is responsible for the allocation of donor hearts in the United States. Allocation is based on urgency (those with highest pretransplant mortality) and benefit gained from transplantation (those with highest post-transplant survival).

Today, we are faced with 2 main challenges regarding donor heart allocation—a rapidly increasing transplant waiting list with a stagnant donor pool and an evolving landscape for device therapies in advanced heart failure. These issues have prompted the proposed revision of the current allocation system. In this review, we discuss history of the allocation system, its current limitations, and how the proposed revision attempts to address these concerns.

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HISTORY OF THE HEART ALLOCATION SYSTEM

In 1968, the U.S. Congress passed the Uniform Anatomic Gift Act which provided the regulatory framework for adults to register as organ donors. In 1984, the introduction of the National Organ Transplant Act enabled the establishment of the OPTN and organ procurement organizations. Four years later, UNOS, acting through its role with the OPTN, finalized the first heart allocation system. The Department of Health and Human Services remained the regulatory body overseeing the OPTN/UNOS efforts to ensure a fair heart allocation system.

The first heart allocation system was a 2-tiered strategy based on urgency, time on waiting list, geography, and blood type. Since its inception, there have been 2 major revisions: a move to a 3-tiered system in 1998 and prioritization of urgency over regional borders in 2005.

These changes led to a marked reduction in the overall waiting list mortality rates without negatively impacting post-transplant mortality.[3] The current 3-tiered system comprises Status 1A, 1B, and 2 in order of highest priority. An overview of the current heart allocation system is provided in Table 1.

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Table 1. Adapted From Organ Procurement and Transplantation Network Policies Dated September 1, 2013[4]

Status 1A	Requires admission to listing transplant center hospital and have at least one of the following indications, devices, or therapies in place
	Acute hemodynamic instability requiring mechanical circulatory support. This may include:
	Total artificial heart
	Intra-aortic balloon pump
	Extracorporeal membrane oxygenation (ECMO)
	Patients with LVAD and/or RVAD are afforded 30 days at any point after implantation if deemed clinically stable
	Patients with significant device-related complications while receiving mechanical circulatory support
	Continuous mechanical ventilation
	Continuous hemodynamic monitoring while receiving continuous infusion of a single high-dose or multiple intravenous inotropes
Status 1B	Requires at least one of the following devices or therapies in place
	LVAD and/or RVAD outside of the 30 days of Status 1A listing
	Continuous infusion of intravenous inotropes
Status 2	Transplant candidates who do not meet criteria for Status 1A or 1B
Status 7	Transplant candidates who are deemed temporarily unsuitable to receive a heart transplant

RVAC, right ventricular assist device.

LIMITATIONS OF THE CURRENT HEART ALLOCATION SYSTEM

Waiting List Dilemma

There has been a proliferation of transplant centers, and the criteria for transplantation have expanded to include older, obese patients with more comorbid conditions, and those with a history of nonadherence and smoking. This has led to more than a twofold increase in the number of active heart transplant candidates over the last decade.[5] As of January 8, 2018, there were more than 3900 candidates listed for heart transplantation.[6]

However, the donor pool has remained stagnant over the past decade and the number of heart transplants performed in the United States has not markedly changed since 1994.[6] The need for an increased "matching of the market" has been highlighted by Hsich.[7]

Inadequate Recognition of Highest Priority Patients

Status 1A listing was initially afforded in rare or urgent cases to patients with an anticipated survival of less than 1 week without transplantation. Currently, 90% of all donor hearts are provided to Status 1A–listed candidates and many of these patients wait more than 6 months for transplantation.[8] The apparent lack of recognition of patients with the greatest need for transplantation leads to excessive numbers of patients listed as Status 1A. This creates a disparity in risk among Status 1A patients and contributes to the excessively high waiting list mortality in this group. The difference in waiting list mortality between Status 1A and 1B candidates is striking (55 vs 17 deaths per 100 patient-years from 2009 to 2013).[3]

Reliance on Status Exceptions Requests

Certain subgroups are overlooked by the current allocation system, leading to a reliance on status exception requests in order to appropriately prioritize transplant candidates.

These subgroups include patients with ventricular tachycardia and fibrillation, adults with congenital heart disease, and those with contraindications to intravenous inotropes or pulmonary artery catheters. These patients comprise 59% of Status 1A and 47% of Status 1B exception requests.[3] Adults with congenital heart disease represent an important population in this setting as the proportion of transplant candidates with adult congenital heart disease has nearly doubled since 1999.[9]

Patients who generally do not receive survival benefit from mechanical circulatory support device implantation are also disadvantaged by the current system as they are difficult to bridge to transplantation. These include adults with congenital heart disease, patients with restrictive or hypertrophic cardiomyopathy, and patients with heart failure with preserved ejection fraction. Although these patients may not have a reduced ejection fraction, they still present with end-stage symptoms, reduced cardiac index, pulmonary hypertension, and poor systemic perfusion.

Geographical Inconsistencies Within the Current System

The OPTN Final Rule for allocation policies states that organ allocation should not be based on a candidate's area of residence listing.[10] However, donor hearts are initially allocated to local Status 1A and 1B candidates and then to any other Status 1A or 1B candidate within 500 miles of the donor hospital. Clearly, these policies are not consistent and have resulted in marked variance in regional waiting list times, as well as certain regions that have more local donors compared with transplant candidates.[11] This has led to some fortunate individuals who can afford relocation to move to areas with shorter transplant waiting times, compromising the ethics of a fair and equitable heart allocation system.[12]

Ethnicity also plays a role in the likelihood of receiving heart transplantation, with Hispanics being disproportionately disadvantaged compared with their white or black counterparts.[13]

Gaming of the Current Allocation System

The current allocation system prioritizes urgency with Status 1A and 1B patients determined by the need for mechanical circulatory