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HEART FAILURE (HJ EISEN, SECTION EDITOR)

Time Is a Precious Commodity: 2018 OPTN Policy Change and the Potential to Lower Heart Transplant Waitlist Time in the Sickest Patients

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Abstract

Purpose of Review Heart transplantation is the gold standard therapy for end-stage heart failure; however, the donor pool is limited, making this a scarce resource that must be allocated to the sickest patients in an efficient, fair, and equitable manner. The allocation policies have been constantly revised over the years to refine the process. We will explore the new heart allocation system, OPTN-Policy 6, as well as, review why these changes were necessary.

Recent Findings Over the past decade, the number of active heart transplant candidates nearly doubled, with a dramatic increase in the number of status 1A and 1B (high priority) candidates. Candidates have also faced increased waitlist times with geographic variances. The allocation policy changes will attempt to alleviate these problems as well as adapt to advances in technology.

Summary The new allocation policy is designed to adapt to the present day reality of expanded mechanical support use, increased candidate acuity, increasing waiting times, and geographical disparities in transplant rates. Though the implementation of the new allocation policy will require some change in practice, the transplant community, as knowledge is gained, is accustomed to change and refinement in practice, in an effort to improve outcomes for patients with end-stage heart failure.

Keywords The Organ Procurement and Transplantation Network · The United Network for Organ Sharing · Thoracic Organ Transplantation Committee · Heart Allocation Policy · Organ procurement organizations · Organ allocation · Regional review boards

Abbreviations

OPTN	The Organ Procurement and Transplantation Network
UNOS	The United Network for Organ Sharing
OPO	Organ procurement organizations
HHS	US Department of Health and Human Services
RRB	Regional review boards
SRTR	Scientific Registry of Transplant Recipients
MCS	Mechanical support

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Introduction

Christiaan Barnard performed the first human to human heart transplant in South Africa over 50 years ago. Over the decades, heart transplantation has become the gold standard therapy for end-stage heart failure. Because this medical wonder is a very limited resource, it is only available to several thousand persons per year. Given that limitation, the transplant community has searched for ways to best allocate donor organs to the sickest patients in an efficient, fair, and equitable manner.

The scarcity of organs, the growing need for this life-saving therapy, and changes in technology have made creating and maintaining the allocation system challenging and, at times, faced with medical and ethical dilemmas. These challenges have been met with perseverance and innovation, and in this article, we will explore the new heart allocation system, as well as, review why these changes were necessary.

Oversight Committees and Policy Development

In the USA, the Organ Procurement and Transplantation Network (OPTN) develops policies and bylaws that govern the allocation of organs and the collection of transplant data. The United Network for Organ Sharing (UNOS) holds the federal contract to operate the OPTN and is responsible for coordinating committee and board actions.

OPTN policies govern the operation of all member transplant hospitals, organ procurement organizations (OPOs), and histocompatibility labs in the US policies and bylaws developed by the OPTN must be forwarded for review and approved by the Secretary of the US Department of Health and Human Services (HHS) to become binding under the authority of federal regulation. The public is included in the process through solicitation of feedback through a public comment process. [1].

During the 1980's, the OPTN created a group of surgeons and cardiologists to review policies and monitor medical, ethical, and scientific issues related to procurement and transplantation. This group, comprised of regional representatives, later evolved into the Heart Transplant Committee, which in the early 1990's took on overseeing all thoracic organ transplantation and is now referred to as the Thoracic Organ Transplantation Committee.

Any changes made to OPTN policies are done in a collaborative process between the OPTN, the transplant community, and the public. Policy changes undergo lengthy evaluation and comment before implementation. When a change in policy is warranted, the Thoracic Committee develops a proposal using the expertise and experience of the transplant community and transplant data provided by UNOS and the Scientific Registry of Transplant Recipients (SRTR).

The potential impact of the proposed policy changes are evaluated in the form of required analyses which include the effects on centers/regions with different transplant volumes, risk-adjusted total life-years pre- and post-transplant, risk-adjusted waiting time, and OPO performance.

For substantive policy changes, the Committee distributes their proposal for public comment for a maximum of 45 days after which the Committee submits a briefing document to the Board of Directors, which then votes on the policy. Approved policies are forwarded to the Secretary of HHS for review and comment a minimum of 60 days before implementation, in accordance with OPTN Final Rule Section 121.4(b) [2]. Policies are re-evaluated periodically by the Thoracic Committee to determine whether they achieve their stated objectives and remain relevant in light of scientific and technological advances [2].

Finally, in an effort to improve center compliance in real-time, Regional review boards (RRB) comprised of local transplant surgeons and physicians are tasked with the oversight of day-to-day quality control in their region. For instance, RRB review request from transplant centers for status extensions and exceptions when candidates do not exactly fulfill the allocation criterion. [3••, 4].

History of the Allocation Process

Organ allocation is based on the equitable distribution of donor organs to those in the most need and likely to survive the transplant procedure. In addition to medical urgency, other practical considerations, such as blood type, distance of the organ to the transplant center (ischemic time), and time accrued on the waitlist are taken into account when allocating an organ.

Over the decades, transplant medicine has evolved, resulting in improved outcomes for transplant recipients. The availability and evolution of both durable and temporary mechanical circulator support (MCS) have increased the survivability of transplant candidates and presented new challenges for the concept of medical urgency for those on the waitlist. In an effort to adapt to changes in the field, the process for allocating organs has evolved as well. In order to gain a better appreciation of the new policy changes, and the potential effects they may have, we should briefly review the previous iterations of the allocation system.

Initially, in 1988, the first iteration of the allocation system was created. This scheme took into consideration medical urgency, waiting time, ischemic time, and blood group. It created a three-tier allocation system of status 1, 2, and 7. Status 1 and 2 included patients who were suitable for organ offers with status 1 patients being the most urgent. Status 7 patients included those who were temporarily unsuitable to receive an organ. In this system, organs were allocated in a sequential fashion based on time accrued in the status to the most urgent candidates (status 1 patients) before an offer to status 2 candidates could be made. In addition to establishing prioritization by medical urgency, geographic zones in divisions of 500 miles were also created.

In 1993, the accrued wait time was addressed. Policy changes were made to permit candidates to receive the waiting time accrued for one thoracic organ while listed for a second thoracic organ, allowed the rollover of time accrued while status 1 to 2, and the ability to transfer multiple thoracic organ transplant to a single thoracic organ. This year also saw some further refinement to the heart-liver transplant enlistment.

The year 1999 was a major year for policy revisions. During that year, we saw the creation of regional review boards (RRB), primary and secondary blood group matching, changes in geographic allocation, and a change in medical urgency prioritization. At that time, status 1 patients included patients on MCS, including total artificial heart (TAH), ventricular assist devices (VADs), intra-aortic balloon pump (IABP), extracorporeal membrane oxygenator (ECMO), and those on ventilator support and/or inotropes. In an effort to decrease waitlist mortality,

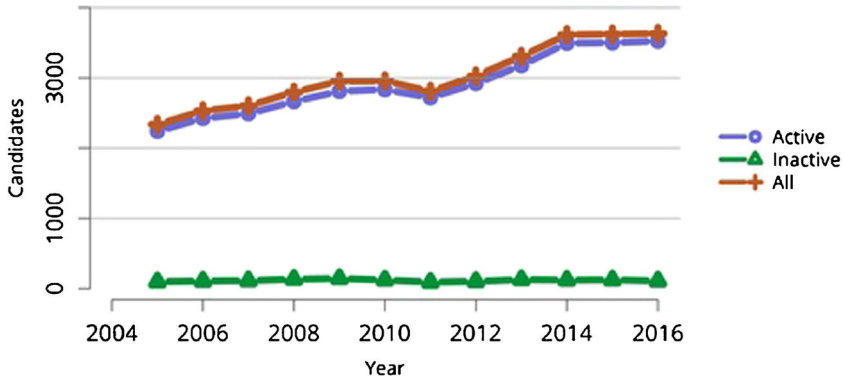

Fig. 1 New adult candidates added to the heart transplant waiting list [5••]

the status 1 medical urgency category was further divided into status 1A and status 1B. Status 1A was assigned to patients with an uncomplicated VAD up to 30 days, VAD complications admitted to the listing transplant center and patients on an IABP, high-dose inotropes with continuous hemodynamic monitoring, or ventilator support. Status 1B was assigned to those on inotropes without continuous hemodynamic monitoring or those who received an exception by the local RRB for status 1B priority. Geographic allocation was also adjusted to allow for the allocation of local donor hearts to local status 1A, 1B, and 2 candidates before offering them to status 1A and 1B candidates in zones A and B.

In the setting of improved MCS device durability and the recognition of worse outcomes for recipients transplanted early after VAD placement, in 2002, the status 1A criterion was further refined. Candidates implanted with VADs were allowed to use 30 days of status 1A time at any time following VAD implantation to allow for post-implant recovery and rehabilitation. Hospitalization was not required when using this criterion for status 1A time.

In 2006, the geographic sequence for organ allocation was modified in an effort to further decrease waitlist mortality. The new allocation sequence allowed for heart offers to both local and zone A, status 1A and 1B candidates before local status 2 candidates; as well as, heart offers to zone B, status 1A and 1B, candidates before zone A and B status 2 candidates. Zones D and E were also created.

Adult outpatients with total artificial heart (TAH) were allowed to be listed as status 1A for 30 days after a 2010 policy addition. The following year required OPOs to provide human leukocyte typing of thoracic organs offered, if requested to do so by the transplant programs receiving the organ-offer. Finally, the policy whereby RRBs examine and approve the request to upgrade the status of candidates with device-related infection or complications was codified. [4].

Why Change Now?

Since the development of the initial allocation system, the demand for heart transplantation has increased while the number of organs remains limited; candidate profiles have shifted to a higher medical urgency which is accompanied with increased waitlist mortality, and more centers are required to request status exceptions for candidates with conditions not amenable to MCS or inotropes in an effort to upgrade their medical urgency [5••, 6, 7]..

Between 2006 and 2015, the number of active heart transplant candidates nearly doubled (Fig. 1) increasing waitlist times, and the number of status 1A and 1B candidates increased dramatically (Fig. 2). The vast majority of organs were allocated to status 1A candidates; whose waitlist mortality is 3× higher than other statuses (Fig. 3, and the number of candidates transplanted on VAD support increased from 9 to

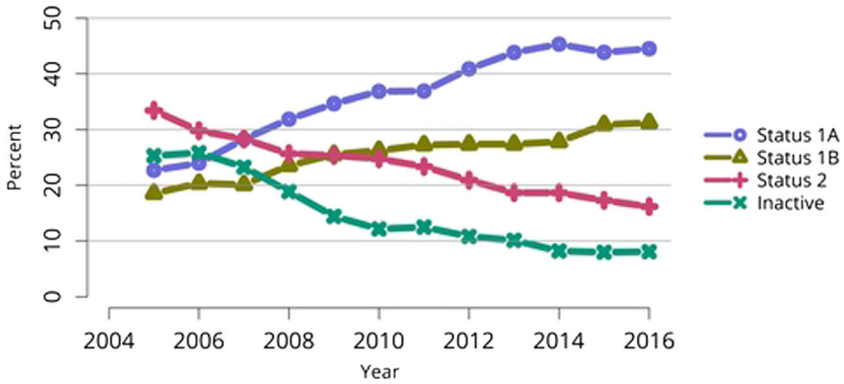

Fig. 2 Distribution of adults waiting for heart transplant by medical urgency [5••]

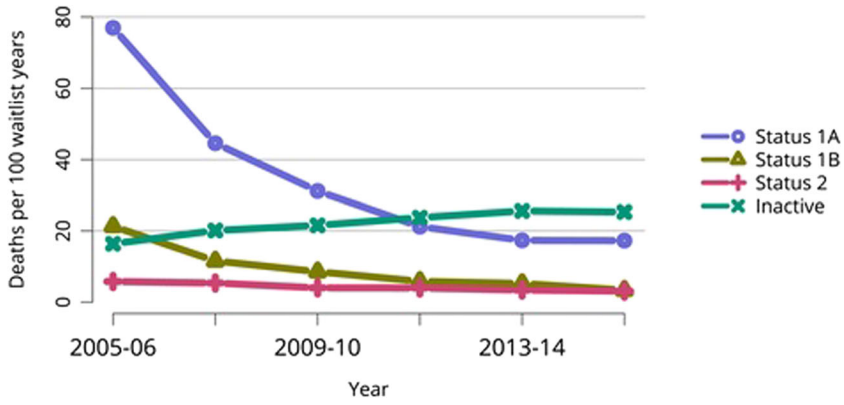

Fig. 3 Pre-transplant mortality rates among adults waitlisted for heart transplant by medical urgency [5••]

24.4%. Finally, significant geographical differences in transplant rates were observed. (Fig. 4) [5••, 6, 7].

To address these issues, the new allocation policy broadens organ distribution across zones, places priority on non-dischargeable MCS devices, codifies cardiogenic shock parameters, better defines and risk stratifies MCS complications, includes candidates that now require status exceptions to increase medical urgency, and shifts local RRB reviews to outside regions.

The new system is comprised of six medical urgency categories. To further risk stratify candidates in cardiogenic shock, the old status 1A category is divided into status 1, 2, and 3. The old status 1B becomes status 4; this tier also includes patients with disorders that are not easily amenable to MCS or inotropes (congenital heart disease, restrictive cardiomyopathy, intractable angina and others). Finally, status 5 includes dual organ candidates, and status 6 for all others (Table 1).

The new allocation policy refines and tightens up the qualification for candidates supported by veno-arterial extracorporeal membrane oxygenation (VA-ECMO), percutaneous circulatory support devices, intra-aortic balloon pumps (IABP), and multiple inotropes by requiring evidence that these candidates are supported by these therapies for treatment for cardiogenic shock, rather than qualifying based on the presence of the therapy alone. To do so, the new status justification forms utilize the definitions established by the American Heart Association for cardiogenic shock or the presence of end-organ dysfunction.

The new allocation system also places additional restrictions on the duration for which candidates stay in status 1–3. Candidates who are supported by therapies intended for short term; use for cardiogenic shock is limited to 14 days in the respective status unless the candidate exhibits contraindications to durable devices and has failed attempts to wean temporary support.

To insure that the objectives of decreasing mortality on the wait list and geographic disparity in transplant rates, while maintaining outcomes for transplant recipients, the Thoracic Committee will systematically evaluate and report the impact of the new OPTN allocation policy, Policy 6, every 6 months for 2 years then annually. The specific questions to be addressed in the post-implementation review process are outlined in Table 2.

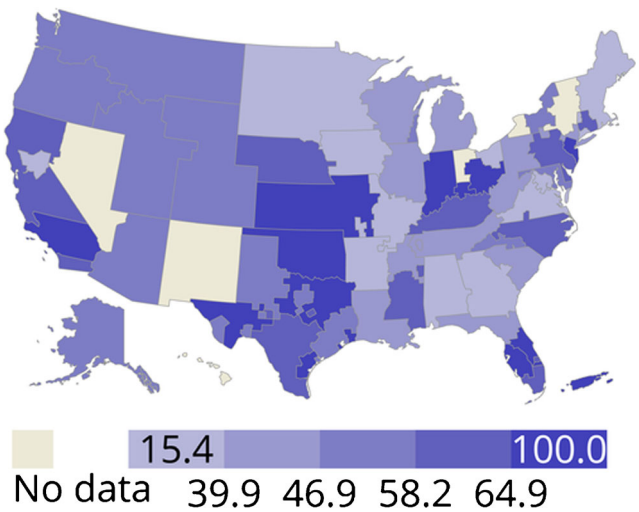

Fig. 4 Percentage of adults who underwent heart transplant within 1 year of listing in 2015 by DS [5••]

Impact of Change on the Providers and Patients

Implementation of the new allocation policy will require more time and resources from transplant providers and centers. More data is required for each candidate during status changes and during the initial transition of candidates registered under the old allocation system to the new. Ironically, there may be some additional cost to centers due to broadening the sharing network. The increase in numbers and distance of organ offers, may require additional hearts fly outs and resources (donor recovery personnel and transplant staff) from programs. This may also affect the OPO practices and costs.

Since the new proposal requires programs to report cPRA data if available, it is unlikely that there will be increased testing cost for the histocompatibility laboratories. From the patient's standpoint, reclassification from the current system

Table 1 Summary of changes to Adult Heart Transplant Status assignments

Previous Allocation System (OPTN Policy 3)	Current Allocation System (OPTN Policy 6)
Status 1A	Status 1
[A] MCS for acute hemodynamic decompensation and at least one of:	VA ECMO
(i) LVAD/RVAD	
(ii) TAH	Non-dischargeable, surgically implanted, non-endovascular biventricular support device
(iii) IABP	MCSD with life-threatening ventricular arrhythmia
(iv) ECMO	
[B] MCS with objective medical evidence of significant device-related complications (infection, thromboembolism, ventricular arrhythmias, mechanical failure, other related complications) approved by heart RRB.	Status 2
[C] Continuous mechanical ventilation.	Non-dischargeable, surgically implanted, non-endovascular LVAD
	IABP
[D] Continuous infusion of single or multiple inotropes in addition to hemodynamic monitoring.	V-tach / V-fib, mechanical support not required
	MCSD with device malfunction/mechanical failure
	TAH, BiVAD, RVAD, or VAD for single ventricle patients
1A exception	Status 3
Candidates who do not meet the above criteria	Dischargeable LVAD for discretionary 30 days
	Multiple inotropes or single high-dose inotrope with continuous hemodynamic monitoring
	VA ECMO after 7 days; percutaneous endovascular circulatory support device or IABP after 14 days
	Non-dischargeable, surgically implanted, non-endovascular LVAD after 14 days
	MCSD with one of the following:
	(i) Device infection
	(ii) Hemolysis
	(iii) Pump thrombosis
	(iv) Right Heart Failure
	(v) Mucosal Bleeding
	(vi) Aortic Insufficiency
Status 1B	Status 4
At least one of the following devices or therapies:	Dischargeable LVAD without discretionary 30 days
(aa) LVAD/RVAD	Inotropes without hemodynamic monitoring
(bb) Continuous infusion of intravenous inotropes	Retransplant
STATUS 1B exception	Diagnosis of one of the following:
Does not meet the above criteria for 1B	(i) Congenital heart disease (CHD)
	(ii) Ischemic heart disease with intractable angina
	(iii) Amyloidosis
	(iv) Restrictive cardiomyopathy
	(v) Hypertrophic cardiomyopathy
Status 2	Status 5
A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.	On the waitlist for at least one other organ at the same hospital
	Status 6
	All remaining active candidates
Status 7	Status 7
A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.	A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Data from [3••]. Based on the Organ Procurement and Transplantation Network (OPTN) Policies as of October 7, 2018. This work was supported in part by Health Resources and Services Administration contract 234-2005-37011C. The content is the responsibility of the authors alone and does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government

to the newer system may cause some growing pains. Both approved and pending exceptions will all be ineffective, and new exception request will need to be filed if the candidate does not quite fit in the equivalent category.

The OPTN has stated that this transition will not cause candidates to lose accrued waiting time. We will likely see more urgent candidates being transplanted, but it is difficult to predict how much this will affect waitlist mortality in the

Table 2 Questions to be addressed in the implementation of Allocation Policy 6

- Have death rates for adult candidates on the heart waiting list decreased?
- Have transplant rates for adult candidates on the heart waiting list increased?
- Have post-transplant survival rates for adult heart recipients changed?
- Has the zonal distribution of heart transplants changed?
- Has the number of exception requests decreased?
- Has the heart utilization rate increased?

Data from [7]. Based on the Proposal to Modify the Adult Heart Allocation System from the OPTN/UNOS Thoracic Organ Transplantation Committee as of October 7, 2018. This work was supported in part by Health Resources and Services Administration contract 234-2005-37011C. The content is the responsibility of the authors alone and does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government

long run [1, 8•] as well as post-transplant mortality. Potentially, if more critically ill patients are prioritized earlier, this may provide more definitive therapy earlier in the recipient's disease course while they are in a more optimal condition.

Post-implementation monitoring is critical to the policy's success so that adjustments can be made if medical or ethical issues arise. Prior to the implementation of OPTN Policy 6, concerns were raised about the frequency of hemodynamic monitoring and appropriate use of MCS to ensuring that non-dischargeable MCS devices are not overutilized [9, 10]. Another area that requires judicious monitoring is the waitlist mortality after the broadening of the sharing zones, especially in those zones with not very productive OPOs or those that have access to a higher volume OPO within 500 miles. Hopefully, higher status patients will have a lower waitlist mortality as they will have access to a wider geographic area. Theoretically, those who do not have access to a productive OPO may not face any changes as they will gain access to additional donors within 500 miles, but only time will tell. It is also difficult to predict how these changes will impact the number of transplants a center will perform, though there will be a noticeable difference in the acuity of the patients being transplanted [8•, 10].

Conclusion

An allocation system that reviews outcomes in a systematic fashion and adapts to changes in practice is key to maintaining the equitable distribution of donor organs to those in the most need and likely to benefit from heart transplantation.

The new allocation policy is designed to adapt to the present-day reality of expanded MCS use, increased candidate acuity, increasing waiting times, and geographical disparities in transplant rates. Though the implementation of the new allocation policy requires some change in practice, the transplant community, as knowledge is gained, is accustomed to change and refinement in practice, in an effort to improve outcomes for patients with end-stage heart failure.

Compliance with Ethical Standards

Conflict of Interest J. Hoosain and S. Hankins declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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