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Review

A Comprehensive Review of the 2018 United Network for Organ Sharing Heart Transplantation Policy Changes

Mohammed Quader[1,2,*], Aditi Patel[2,3], Krishnasree Rao[2,3], Melissa Smallfield[2,3]

[1]Division of Cardiothoracic Surgery, Department of Surgery, Virginia Commonwealth University, Richmond, VA 23298, USA
[2]Pauley Heart Center, Virginia Commonwealth University Health System, Richmond, VA 23298, USA
[3]Division of Cardiology, Department of Internal Medicine, Virginia Commonwealth University, Richmond, VA 23298, USA
*Correspondence: mohammed.quader@vcuhealth.org (Mohammed Quader)
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Abstract

Background: Historically, the heart allocation process relied heavily on local organ procurement organizations and geographic proximity, leading to disparities and inequitable outcomes driven by regional donor availability rather than clinical urgency. The 2018 revision of the heart transplantation allocation policy by the United Network for Organ Sharing (UNOS) significantly transformed the landscape of heart transplantation in the United States. This review critically examines the rationale, implementation, and impact of these policy changes, focusing on their effectiveness in addressing longstanding shortcomings, including geographical disparities, inadequate clinical risk stratification, and remaining challenges. **Methods**: A detailed review of published literature on the heart allocation system and national data from the Scientific Registry of Transplant Recipients was conducted. **Results**: The new heart allocation system significantly reduced waitlist mortality, from 139 deaths to 114 deaths per 100 patient-years, among the highest urgency patients. Meanwhile, median wait times for Status 1 candidates decreased from 112 to 39 days. The new policy particularly benefited patients assisted with temporary mechanical circulatory support devices such as extracorporeal membrane oxygenation (ECMO), intra-aortic balloon pumps, and Impella devices, whose transplantation rates increased substantially. Indeed, one-year survival rates for patients supported by ECMO improved after policy adoption (90% post-2018 vs. 74% pre-2018). However, the broadened geographic radius (500 nautical miles) intended to enhance equity promoted increased ischemic times (from 3.0 hours to 3.4 hours), raising concerns about long-term graft viability. Financial and logistical implications, such as increased organ transportation costs and resource utilization, were notable challenges. Additionally, stable patients with durable left ventricular assist devices (LVADs) experienced deprioritization unless complications arose, raising concerns about prolonged wait times and associated morbidity. Thus, despite clear improvements, persistent challenges remain. **Conclusion**: The changes to the heart allocation system brought significant benefits to the patients with high acuity status listings; however, some challenges remain. Meanwhile, the transition to a continuous distribution model, which employs a composite allocation score, holds promise for further refining patient prioritization by balancing medical urgency, geography, post-transplant survival predictions, and biological factors. Nonetheless, enhancements in donor organ preservation, standardized exception request processes, and optimized allocation algorithms remain essential to sustain the fairness, efficiency, and clinical effectiveness of the system.

Keywords: heart transplantation; organ allocation policy; waitlist mortality; heart transplantation outcomes

Introduction

Historical background of heart transplantation waitlist development: Heart transplantation has undergone dramatic shifts since the first successful heart transplant, performed in 1967 by Dr. Christiaan Barnard in Cape Town, South Africa [1]. This landmark achievement ushered in a new era of medical treatment for end-stage heart failure, providing a viable therapeutic option for patients previously left without effective alternatives. This procedure also introduced challenges that were not previously considered, such as defining brain-dead donors and the need for fair allocation of hearts to the patients most in need. In the initial stages, donor hearts were allocated locally, primarily based on geographical proximity between donor hospitals and recipients, with minimal consideration given to the medical urgency of the patients. This proximity-based approach was pragmatic at the time due to limitations in organ preservation and transportation technologies; however, the approach soon proved inadequate as distant procurement and viable storage of donor hearts for transplantation became a reality [2]. The problem was further compounded by the growing number of patients listed for heart transplantation and the limited number of available heart donors, leading to increasing mortalities of patients on the waitlist [3]. Thus, the growing discrepancy between donor organ availability and the increasing number of patients on waitlists exposed inherent flaws in this allocation system [4].

Recognizing the need for a more equitable distribution system, the United States Congress enacted the National Organ Transplant Act of 1984 [5,6]. This pivotal legislation led to the establishment of organ donation regulations under the supervision of the Department of Health and

Human Services' Organ Procurement and Transplantation Network (OPTN), a national system charged with overseeing and standardizing organ donation and allocation across the United States (OPTN Website: https://optn.transplant.hrsa.gov/). Under the direction of the United Network for Organ Sharing (UNOS), this new system aimed to prioritize transplantation candidates based on clinical urgency and the severity of their illness, rather than geographical proximity, to provide equitable access to donor organs nationwide. The initial system had two tiers based on the severity of the disease, geographical location, wait time, and blood group [7].

Over the subsequent decade, the transplantation landscape was profoundly transformed by advances in mechanical circulatory support (MCS) devices, particularly left ventricular assist devices (LVADs) [8–10]. Initially introduced as temporary solutions ("bridges to transplant"), LVADs significantly extended survival for patients awaiting heart transplantation, enabling many to remain stable for prolonged periods [10]. However, the widespread adoption of LVADs over time introduced new complexities to the allocation process. While LVAD-supported patients benefited from reduced short-term mortality compared to patients experiencing acute cardiogenic shock, these patients remained at considerable risk for complications associated with prolonged mechanical support, such as infections, device malfunction, and stroke [11]. Consequently, the allocation system faced the challenge of appropriately balancing the urgency of LVAD-supported patients against those experiencing acute instability without device support [12].

To address these growing complexities, the Department of Health and Human Services issued the Final Rule in 1998, directing that organ allocation should be prioritized based on medical urgency and should not be influenced by recipient location [13]. This led to the establishment of a three-tiered status classification (Status 1A, 1B, and 2). Status 1A represented the highest urgency and was reserved for critically ill patients who required continuous mechanical support or faced imminent risk of death without a transplant. Status 1B patients included those with stable LVAD support or significant medical management needs, while Status 2 encompassed medically stable patients awaiting transplantation. The Department of Medicare and Medicaid also established 57 donor service areas (DSAs) across the United States, each managed by a local organ procurement organization (OPO) [14]. Although this three-tiered system improved patient stratification by medical urgency, it was soon recognized that further refinements were necessary, particularly in addressing persistent geographic disparities [4,12]. OPTN/UNOS replaced the DSA system with "acuity circles", but this had a limited impact on the intended benefits of addressing geographical disparities [14].

Shortcomings in the Previous System

Over the years, the number of heart transplants has increased significantly, with more than 4000 transplants performed annually [3,15]. More importantly, the number of patients added to the waitlist grew rapidly. Subsequently, the number of candidates added to the waitlist doubled between 2006 and 2015, leading to a significant increase in wait times for transplantation [16]. Heart transplants were predominantly performed for patients listed under the 1A category, who also had a waitlist mortality rate three times that of other groups [16]. Similarly, the percentage of patients transplanted with LVAD support increased from 9% to 24.4%, with the vast majority being uplisted for MCS complications under exceptions [3,15,16].

By the early 2000s, the limitations of the three-tiered system had become increasingly evident [17,18]. Moreover, geographical disparities posed substantial ethical and clinical challenges [18]. Furthermore, the reliance on donor service areas (DSAs) created notable imbalances in access to donor organs. Patients residing in regions with less densely populated areas often endured significantly longer wait times and higher waitlist mortality rates compared to those living in metropolitan areas [18]. Consequently, regional differences in organ availability rather than clinical urgency often dictated transplantation opportunities, contributing to inequitable patient outcomes [4,12,19].

The previous system also suffered from inadequate risk stratification. The broad classification within Status 1A did not adequately differentiate between varying degrees of patient illness [11,17,18]. For instance, patients requiring continuous high-dose inotropic therapy but maintaining relatively stable hemodynamics were grouped alongside critically ill individuals experiencing severe cardiogenic shock and reliant on ECMO support. Similarly, patients with life-threatening LVAD complications (e.g., LVAD thrombosis) were grouped together with those experiencing less severe complications (e.g., LVAD-associated gastrointestinal bleeding) [11]. Due to a lack of rigorous definitions for the severity of illness, patients were assigned to a high-acuity status based on the treatment they received, rather than the required treatment [4]. Consequently, less urgent patients sometimes received transplants ahead of those facing imminent mortality risks, thereby exacerbating waitlist mortality and reducing overall fairness [12,14,16].

Finally, the excessive use of exception requests created additional challenges, as the acuity of the illness did not conform to the existing listing criteria [20,21]. Patients with restrictive cardiomyopathies, congenital heart disease, arrhythmias, and intractable angina who could not be supported through durable MCS were often up-listed via exception listings [22]. However, frequent exception submissions to elevate patient statuses added an administrative burden and introduced significant variability, resulting in subjective, inconsistent prioritization across transplant centers and undermining the transparency and fairness of

Table 1. Summary of the differences between the pre- and post-2018 systems.

Feature	Pre-2018 system	Post-2018 system
Listing status categories	Status 1A, 1B, 2	Status 1, 2, 3, 4, 5, 6
Geographic allocation	Local DSAs with concentric zones	500-mile radius for Status 1 and 2
Use of mechanical support	Durable LVADs categorized under Status 1B	Increased prioritization of temporary MCS (ECMO, IABP, Impella over durable LVADs)
Waitlist mortality	Higher in the heterogeneous Status 1A group	More refined stratification, reduced mortality in high-status groups
Exception requests	Frequently required for nuanced cases	Despite explicit criteria for each status, more exceptions are requested

DSA, donor service area; LVAD, left ventricle assist device; MCS, mechanical circulatory support; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump.

the overall allocation process [4,12]. Collectively, these shortcomings underscore the need for a more robust, clinically responsive allocation approach, eventually culminating in the comprehensive policy reforms implemented by OPTN/UNOS in 2018 [12,14,23].

Intended Objectives of the New System

The goals of the 2018 UNOS policy changes were applied to promote:

• Better risk stratification: Six categories (Status 1, 2, 3, 4, 5, and 6) of listing were created that would allow for more precise classifications of heart transplant candidates based on clinical needs, such as hemodynamic instability, the use of MCS, and other objective criteria (Table 1).

• Prioritization of the sickest patients: Patients on ECMO, IABP, and those with highly unstable hemodynamics were given higher priority, ensuring that the sickest patients received timely transplants.

• Adoption of a unified definition of cardiogenic shock: The policy adopted the American Heart Association (AHA) definition of cardiogenic shock, guiding the listing process with an objective criterion. The policy also required high-status renewals every 1–2 weeks.

• Elimination of geographic disparities: The policy introduced a 500-mile radius for organ allocation, moving away from the local DSA-based allocation. This enabled a more equitable distribution of organs, particularly benefiting patients in regions with limited donor availability.

• Reduction of exception requests: By refining the definitions of medical urgency and status categories, the policy aims to reduce the need for exception requests, streamline the allocation process, and improve consistency.

Key Differences Between the Pre-2018 and New System

The post-2018 system introduced a more refined six-tier system (Statuses 1–6), allowing for a more precise categorization of high-acuity patients based on objective data and their specific clinical needs, enhancing the efficiency of the allocation process and ensuring timely transplants for the sickest patients [23]. The geographical allocation model also underwent significant changes. Under the pre-2018 system, organs were primarily allocated based on local DSAs, which led to regional disparities in access to donor hearts. The 500-mile radius organ sharing reduced these geographical inequities and improved access for patients in underserved areas.

The use of mechanical support devices was also restructured. Under the old system, the majority of 1A-listed patients had heterogeneous complications resulting from durable LVAD support and were competing for the donor hearts with patients supported with temporary MCS [24]. The new system refined the assessment of patient illness acuity more objectively, and priority was provided to ECMO, IABP, and Impella-supported patients, whose waitlist mortality rates were higher [16,25]. The most significant benefit of these changes was the reduction in waitlist mortality, achieved by improving risk stratification (Table 2) [12].

Impact of the New System

Waitlist mortality and waitlist times: The implementation of the 2018 UNOS heart transplantation allocation policy significantly improved critical outcomes for waitlisted patients, notably reducing waitlist mortality and shortening wait times, particularly for the most urgent patient categories [26]. The new allocation system, characterized by more precise clinical stratification and broader geographical organ sharing, facilitated more timely and equitable access to donor hearts.

While the number of patients added to the heart transplantation list is comparable pre- and post-2018 policy changes, a greater number of patients were listed under high-priority status (1,2,3) compared to before the policy change: 35% vs. 25%, respectively [27]. Similarly, a higher number of patients listed under high-priority status (1,2,3) received heart transplants, 78% compared to 68% before the change [27]. It is worth noting that, although the overall patient acuity profile did not change significantly following the adoption of the new system, the number of patients added to the waitlist with high acuity status increased significantly [28].

Table 2. Detailed policy changes between pre-2018 and post-2018.

Heart transplantation waitlist groups	Objectives for the new system	Heart transplantation waitlist groups	Remaining needs
Before October 2018		**After October 2018**	
1A- -Acute hemodynamic decompensation supported with (a) LVAD or RVAD (b) IABP (c) ECMO (d) TAH	Priority is based on the acuity of the illness.	**Status 1** -On ECMO support (up to 7 days)* -On non-dischargeable surgically implanted VAD -On MCSD with life-threatening ventricular arrhythmia	Priority is given to patients receiving a specific treatment with or without an objective need for the treatment.
		Status 2	
-MCS-related complication (a) Device infection (b) Thromboembolism (c) Ventricular arrhythmia (d) Mechanical failure (e) GI bleed or other complications	Distinguish between different device-related complications to prioritize listing.	-On intra-aortic balloon pump support (up to 14 days)* -Sustained ventricular tachycardia/ventricular fibrillation -Non-dischargeable, surgically implanted, nonendovascular LVAD (up to 14 days)*	Too many exceptions were requested to account for undefined complications.
-Continuous ventilatory support -Continuous single or multiple inotropes plus continuous hemodynamic monitoring -LVADs for 30 days -Exceptions to the above approved by RRB	Debated the need for 30-day exceptions.	-MCSD with device malfunction/mechanical failure -Total artificial heart -Dischargeable BiVAD or RVAD -Acute endovascular percutaneous circulatory support (up to 14 days)*	The 30-day provision remains.
		Status 3	
		-Dischargeable LVAD for up to 30 days -Multiple inotropes or single high-dose inotropes with continuous hemodynamic monitoring -MCSD with device infection, hemolysis, pump thrombosis, right heart failure, mucosal bleeding, and aortic insufficiency -ECMO after 7 days or any other temporary MCSD after 14 days	
1B- Status 1B -LVAD-supported patients with stable hemodynamics	Durable LVAD patients with no complications had long wait times.	**Status 4** -Stable LVAD candidates not using the 30-day discretionary period	The wait times increased further, LVAD patients are transplanted when the device-related complication emerges.
-Continuous inotrope infusion -1B exception approved by the RRB	No provision for patients with restrictive CMP and congenital heart diseases.	-Inotropes without hemodynamic monitoring -Congenital heart disease -Ischemic heart disease with intractable angina -Hypertrophic cardiomyopathy -Restrictive cardiomyopathy -Amyloidosis -Re-transplant	Increased number of appeals for the special group of patients with advanced HF.

Table 2. Continued.

Heart transplantation waitlist groups	Objectives for the new system	Heart transplantation waitlist groups	Remaining needs
Before October 2018		**After October 2018**	
	New provision for patients in need of combined organ transplantation.	**Status 5** -Combined organ transplants	Higher need for dialysis post-transplantation, concerning for appropriate prioritization.
2- -Candidates not listed for 1A or 1B but are eligible for heart transplantation	None.	**Status 6** -All other listed candidates	None.
7- -Temporarily not suitable for transplantation	None.	**Status 7** -Inactive candidates	None.

RVAD, right ventricle assist device; TAH, total artificial heart; VAD, ventricle assist device; MCSD, mechanical circulatory support device; RRB, regional review board; BIVAD, biventricular assist device. *, reapply for status maintenance every 1 or 2 weeks.

Before 2018, patients on ECMO or IABP were frequently disadvantaged by inadequate prioritization, resulting in prolonged wait times and higher mortality rates [16]. One of the most notable impacts was the substantial decrease in waitlist mortality among high-priority patients [27,29–31]. Before the implementation of the new system, Status 1 patients faced waitlist mortality rates as high as 139 deaths per 100 patient-years; however, following the policy changes, this rate notably decreased to 114 deaths per 100 patient-years [3]. In a study examining ECMO-supported patients awaiting heart transplantation, the new system led to a significantly reduced wait time on ECMO (4 days vs. 7 days) and waitlist mortality, with rates of 6.3% vs. 19.3%, respectively [25]. This improvement was primarily attributed to the refined categorization of acutely ill patients into three groups (Status 1, 2 or 3) from a previous single group (1A), thus ensuring patients with acute cardiogenic shock, particularly those supported by temporary MCS, such as extracorporeal membrane oxygenation (ECMO) or Impella, received more immediate prioritization [4,14]. Post-implementation data revealed that in addition to shorter wait times, the ECMO-supported patients experienced substantially reduced mortality rates, highlighting the effectiveness of the new status categories in accurately reflecting the urgency and complexity of the medical conditions of these patients [12,25,30].

Simultaneously, median waitlist times dramatically decreased under the new allocation system [29,31–33]. Specifically, median waitlist times for high-priority Status 1 patients dropped from 112 days to approximately 39 days [12]. This significant reduction was directly associated with broader geographical sharing policies, which expanded the donor–recipient matching radius to 500 nautical miles for the highest-urgency categories (Status 1 and 2). Consequently, critically ill patients had quicker access to donor organs regardless of geographical disparities, thereby mitigating previously existing regional inequalities [14].

However, the new system did introduce some unintended complexities. The increased geographical radius, while beneficial for equity and reduced wait times, resulted in longer ischemic times due to extended transportation distances [33]. Thus, ischemic times increased modestly from an average of 3.0 hours to approximately 3.4 hours post-policy [4,26]. Though this raised concerns regarding potential long-term effects on graft viability and survival, short-term outcomes appeared unaffected, and overall post-transplant survival remained stable or slightly improved [14,34]. Continuous assessment of these outcomes is crucial, as balancing shorter waitlist times with potential impacts on graft quality will remain a key challenge in the future [4,14].

Post-transplantation outcomes: The implementation of the 2018 UNOS heart transplant allocation policy has had a noticeable impact on post-transplant survival outcomes, although the initial results have been mixed [34]. It is important to note that several factors, including waitlist mortality, timely access to transplants, and the quality of donor hearts, have played significant roles in shaping post-transplant outcomes for patients, especially those categorized as having the highest priority status (Status 1). While some aspects of post-transplant survival have improved, such as for those patients supported with MCS, concerns about ischemic times and graft function have arisen due to the broader allocation radius [33].

Short-term survival rates (1-year survival) have shown improvements under the 2018 policy, particularly for Status 1 patients [35,36]. One of the most significant improvements was observed in ECMO-supported patients, where the six-month post-transplant survival rate increased significantly, from 75.9% to 94.2% [14,25]. While post-transplantation survival is multifactorial, the timely transplantation, facilitated by the revised allocation system, contributed to this improved outcome [4,12]. Similarly, long-term survival rates (3 years post-transplant) have also im-

proved for ECMO patients under the new policy, 87% vs 66.4%. This improvement reflects a decrease in early post-transplant mortality and suggests improved management of high-risk transplant candidates. The broader allocation criteria enabled by the 500-mile sharing radius allowed more critically ill patients to receive hearts in a timely manner, preventing the complications associated with prolonged wait times [25]. Subsequently, early complications, such as primary graft dysfunction and acute rejection episodes, have been reduced, leading to improved early survival outcomes for these patients [31]. The substantial survival improvements observed under the new listing system in high-acuity Status 1 and 2 patients were not seen in less acutely ill patients, Status 3–6, where the survival numbers remained comparable [3].

While the changes to revised listing criteria have improved access to donor organs for patients in underserved areas, these changes have also introduced potential risks to organ preservation. Prolonged ischemic times can lead to delayed graft function, increased risk of primary graft dysfunction, and, in some cases, reduced long-term survival due to the damaging effects of prolonged cold ischemia on donor hearts [26]. Additionally, the impact of ischemic injury, particularly in older patients or those with extended donor–recipient transport distances, may further challenge long-term graft survival.

While concerns about longer ischemic times persist, evidence from the early years post-policy implementation suggests that this factor has not significantly compromised short-term survival. The improvements in patient stratification and timely access to transplants have outweighed the potential risks of increased ischemic time, at least in the initial post-transplant period [4,14]. However, the potential for long-term adverse effects due to extended ischemic periods remains a point of caution for clinicians and transplant centers alike. Thus, close monitoring of ischemic times and post-transplant graft function should continue as research and improvements in organ preservation techniques continue to evolve [4,16,26].

Donor characteristics and procurement distance: A significant aspect of the 2018 UNOS heart allocation policy was the transition from locally based donor organ allocations to broader geographical sharing, introducing a 500-mile radius for organ procurement. This modification was designed primarily to alleviate geographical disparities and ensure equitable access to donor organs across different regions. However, this change has had notable implications, particularly concerning donor organ characteristics, procurement logistics, and subsequent ischemic times [4,26]. The prevalence of longer ischemia times (>6 hours) in the UNOS database increased post-implementation from 18.5% to 22% [37]. It is worth noting that longer ischemia times are also associated with decreased one-year survival, 87.5% vs. 90.9% [37].

Despite these concerns, the broader radius has positively impacted equity and patient access, particularly benefiting patients in historically donor-deficient regions. This has been reflected in a more balanced national organ distribution, reducing regional disparities in transplant rates and waiting times [3,4]. Moreover, expanded geographical sharing has promoted access to higher-quality donor organs that were previously unavailable due to stringent geographical constraints, potentially offsetting some of the negative consequences of increased ischemic times. Meanwhile, the continued emphasis on improving preservation methods, such as advanced organ perfusion techniques, is essential to mitigate ischemia-related damage and maintain high-quality transplant outcomes. Ongoing monitoring and adaptation of preservation techniques and logistical processes are crucial in balancing improved geographical equity with the preservation of optimal donor organ function [14,26].

Transportation costs: The distance between donor hospitals and transplant centers has increased following the introduction of the broader 500-mile radius for organ procurement, leading to higher transportation costs [25,38]. According to prior studies, the average travel distance increased from 193 miles pre-policy to 269 miles post-policy, contributing to an increase in average transportation costs from approximately USD 2500 to USD 3500 per organ [26,38]. While these costs are significant, these costs are part of a broader effort to improve organ access, particularly for patients in underserved areas where donor availability is limited [39].

Hospitalization costs and length of stay: The hospital length of stay (LOS) for heart transplant patients has remained relatively stable despite the introduction of changes in the listing criteria. Studies have indicated that inflation-adjusted costs per transplant have risen by an average of USD 40,000 [39,40]. This increase is primarily attributed to the wider use of temporary MCS devices, such as ECMO, which often requires intensive care unit (ICU) stay and higher inpatient costs [4]. Despite these increases in the cost of heart transplantation, one of the potential benefits of the policy change is that it has led to reduced waitlist mortality rates, particularly among high-risk patients with severe heart failure or those requiring mechanical circulatory support [12]. The timely transplantation of these patients has reduced the need for extended ICU stays and other intensive medical interventions [14]. Additionally, studies suggest that patients who receive earlier transplants experience fewer complications and shorter hospital stays, leading to lower inpatient costs compared to those who face longer hospitalizations secondary to complications arising while waiting for transplantation or from post-transplantation complications [3,40].

Multi-organ transplants: The 2018 UNOS heart transplant allocation policy changes had significant implications for multi-organ transplants, particularly the broader organ

sharing radius and refined status categories, which altered the dynamics of how heart–liver, heart–lung, and heart–kidney transplants are allocated and managed [41]. The wait times and mortality rates of patients awaiting multi-organ transplants decreased while the post-transplantation outcomes remain comparable [42]. One of the key changes noted in heart–kidney transplants is the increased dialysis requirements post-transplant. Studies have shown that dialysis dependency post-transplant is a significant risk factor for increased mortality, as it is associated with higher rates of infection, delayed graft function, and cardiovascular complications [3,4]. While the 2018 policy has improved timeliness in organ access for high-priority patients, these complex transplant cases still face significant challenges post-operatively due to the combined organ management. In contrast, heart–liver and heart–lung transplants have remained stable in terms of post-transplant outcomes, with no significant decline in long-term survival rates [42]. The improved allocation system has allowed for improved, timely organ availability and more efficient matching for multi-organ candidates. The stability in heart–liver and heart–lung transplants suggests that, while these policy changes have introduced logistical complexities, the clinical outcomes for these dual-organ recipients have not been adversely affected by the new allocation system [12,14,26].

Special patient populations: The 2018 UNOS heart transplant policy changes had a significant impact on patient populations with less common but unique cardiac physiology, such as those with restrictive cardiomyopathy, congenital heart diseases, and patients with high panel reactive antibodies (PRAs). These policy changes were aimed at improving equity, efficiency, and urgency-based prioritization for these specific groups.

For patients with restrictive cardiomyopathy, the 2018 policy changes offer improvements in prioritization for those patients with severe symptoms [43]. Before the policy shift, these patients were often classified under Status 1B, leading to inconsistent prioritization. The new system enables improved stratification of clinical urgency, prioritizing those with more advanced symptoms or worsening cardiac function. However, stable patients with less severe manifestations of the disease are now deprioritized, leading to increased wait times unless these patients experience complications such as heart failure or arrhythmias [4,14].

Patients with congenital heart disease (CHD), particularly those with complex repaired defects, benefited from the expansion of organ sharing and more precise stratification of patients based on medical urgency [44]. The broader organ-sharing radius improved access to donor hearts, especially for adults with congenital heart defects who previously had extended wait times. However, the multi-organ involvement seen in many CHD patients remains a challenge under the new system [4].

Historically, patients with high PRA levels were at a disadvantage in the allocation process. While these patients benefit from the more refined allocation system, they still face challenges, including longer wait times, due to their high sensitization. The new system balances sensitization with other clinical factors, but patients with high PRA still face delays, highlighting the need for further improvements in organ allocation fairness [12,26].

The appeals process: The appeals process for heart transplant patients to the Regional Review Board has long been a significant aspect of the organ allocation system, allowing transplant centers to request a higher priority status for patients who do not meet traditional criteria but are still in urgent need of a transplant. The 2018 UNOS heart transplant policy changes aimed to improve the allocation process by refining patient stratification and reducing the need for exception requests.

However, data indicate that the use of exception status listings has increased post-implementation [12,45]. Indeed, before the policy change, exception status listings were relatively infrequent. Between November 1, 2015, and October 17, 2018, 9624 adult candidates were listed for heart transplantation, with 328 (3.4%) of these listed with an exception status at the time of initial listing [3,12]. Following the policy implementation, there was a notable increase in exception status listings. Between October 18, 2018, and September 30, 2021, 9589 adult candidates were listed, with 1704 (17.8%) listed by exception at initial listing—a more than fivefold increase compared to the pre-policy period [12,45]. The majority of the appeals (95.7%) were approved for listing. This was a surprising finding as the policy change was expected to result in a reduction of appeals. In addition, the percentage of candidates transplanted while listed by exception increased post-policy, whereby 10.0% of transplanted candidates were listed by exception at the time of transplantation in the pre-policy period; this figure rose to 32.3% in the post-policy period, indicating a more than threefold increase [3,12].

Thus, further refinements are needed to make the appeals process more efficient and equitable. Additionally, improving transparency in clinical criteria, enhancing real-time monitoring of patient status, and utilizing data analytics to assess the long-term impact of exceptions would help streamline the process. Furthermore, centralizing decision-making and ensuring consistent application of rules could improve fairness and reduce regional disparities in how appeals are handled.

Use of Mechanical Circulatory Support (MCS) Under the New System

One of the most profound impacts of the 2018 UNOS heart transplant allocation policy is the increased integration and prioritization of patients supported with MCS devices, which have significantly reshaped the management and outcomes of critically ill transplant candidates. The refined policy delineated two categories of MCS: durable

MCS and temporary MCS (tMCS), each of which plays a distinct role within the allocation framework and patient outcomes [14,15].

Durable mechanical circulatory support: Durable MCS primarily refers to LVADs, designed for prolonged patient support, either as a bridge to transplant (BTT) or as destination therapy. Under the previous allocation system, patients with LVADs were predominantly categorized as Status 1B, leading to intermediate priority on the waiting list.

The 2018 UNOS heart allocation policy significantly affected patients supported by durable LVADs, resulting in a complex mix of positive and negative outcomes. Historically, patients with LVADs were predominantly classified under Status 1B, giving them moderate prioritization within the heart transplantation waitlist. However, under the revised policy, stable LVAD-supported patients without complications were typically assigned lower priority statuses (Status 4), effectively deprioritizing their urgency for transplantation [4,14,46]. Consequently, these patients experienced longer waiting periods due to reduced prioritization, unless significant device-related complications, such as device thrombosis, stroke, infection, or recurrent heart failure, arose, which would prompt a change to a higher urgency status (Status 2 or 3). Despite the general deprioritization of stable LVAD patients, the overall median wait time for LVAD-supported patients decreased notably, from 139.5 days pre-2018 to 37 days post-policy implementation [3]. This substantial reduction was largely attributable to LVAD patients experiencing complications and being reassigned to a higher status.

With the 2018 policy changes, the prioritization of stable LVAD patients was adjusted downward (Status 4), significantly altering their position on the transplant waitlist [4]. This adjustment aimed to improve the reflection of the reduced immediate mortality risk for stable LVAD patients compared to those on tMCS. However, if durable LVAD patients experienced complications, such as device infection, thrombosis, or recurrent heart failure, these patients were assigned higher urgency categories (Status 2 or 3), thereby accurately reflecting their clinical urgency [14]. This change has reduced the use of LVADs as BTT, with a simultaneous increase in the number of annual heart transplants [30,47]. A 2021 study of the UNOS database for adults with durable, continuous-flow LVADs at listing or implanted while listed between April 2017 and April 2020 showed a decrease in the proportion of patients with LVADs at the time of transplant from 47% to 14% [48]. However, the study found that transplantation rates were not significantly different (85.4% vs. 83.6% post-policy change); however, the waitlist time decreased from 82 days to 65 days. Post-transplantation survival was worse in patients with BTT post-change. The study by Mullan *et al.* [48] suggested that there are far more patients undergoing transplant as a primary therapy versus receiving LVAD. There is also a signal of prioritization for patients supported by tMCS, as well as a decline in the number of listed patients receiving LVADs. The 2022 annual report from the Society of Thoracic Surgeons reported a decrease in the implantation of primary LVADs, representing a 23.5% reduction in the yearly volume compared to the peak in 2019, attributing this reduction to the effects of the coronavirus 2019 pandemic and the change in the United States heart transplant allocation system in 2018 [49]. The 2018 allocation change demonstrated a decline in the proportion of transplant-eligible patients receiving a transplant from 56.5% to 46.0%, at 3 years. However, the proportion of patients alive with ongoing, durable MCS has improved from 24.1% to 38.1% at 3 years, suggesting an improvement in LVAD technology and a better adverse events profile, with significant reductions in stroke, gastrointestinal bleeding, and hospital readmissions [49,50]. This refined prioritization balanced the needs of stable LVAD-supported patients against those of more urgent candidates. However, it raised concerns regarding longer wait times and potentially increased complications from prolonged LVAD support in clinically stable patients [3,4,12]. Before 2018, the 1-year post-transplant survival rate for durable LVAD-supported patients was approximately 85%; however, following the policy implementation, survival rates improved marginally, increasing to around 87–88% [3,14,48]. This modest improvement suggests that the new allocation system successfully prioritizes patients with LVADs who are at the greatest risk, reducing complications associated with prolonged device support and enhancing overall patient outcomes.

A notable shift in the allocation process is the increase in the percentage of MCS patients receiving heart transplants. Before 2018, approximately 30% of heart transplant candidates were supported by LVADs. Since these policy changes, the number of heart transplant recipients has increased to over 40% of all heart transplant recipients [14,15]. This rise reflects the improved prioritization of patients who have transitioned to mechanical circulatory support as a bridge to transplant, particularly those experiencing complications that elevate their urgency level. Nevertheless, stable LVAD patients without complications now face prolonged wait times, increasing their exposure to potential device-related complications. Therefore, ongoing evaluation of clinical outcomes, particularly long-term survival and quality of life, remains essential to ensure that the benefits of rapid transplantation for complicated LVAD cases outweigh potential harms to stable patients [4,14].

Temporary mechanical circulatory support: The use of tMCS devices, such as IABPs, Impella devices, and ECMO, has become more prevalent in the current system as patients supported with these modalities are deemed more critically ill and prioritized over those requiring only inotrope support. The most notable change in the six-tier system provides patients supported by tMCS higher priority, specifically those on ECMO, versus those supported by a durable

MCS or patients supported by inotropes alone [51]. A retrospective analysis of data from the National Inpatient Sample from 2017 to 2020 identified recently published data on hospitalizations for cardiogenic shock, stratified by pre- and post-policy changes [52]. Steitieh *et al*. [52] reported a decrease in the use of durable MCS and an increase in cardiac transplantation. The authors also showed that tMCS use declined in general cardiogenic shock patients; however, the use increased in those who received cardiac transplants across various tMCS modalities, including IABP, Impella, and ECMO. Multiple studies of both individual institutional data and registries support the increased priority of tMCS modalities over dMCS [33,53,54]. Thus, these devices play a vital role in the current system as short-term bridge therapies to stabilize patient hemodynamics until transplantation occurs [12].

IABP (intra-aortic balloon pump): Under the new policy, IABP utilization increased markedly from 5.3% pre-implementation to 10.3% post-implementation [12]. A cohort study published in 2020 from the Critical Care Cardiology Trials Network reported a higher proportion of admissions for acute decompensated heart failure with cardiogenic shock supported by IABP after the UNOS allocation system change from 25.4% (32 of 126 admissions) to 42.6% (52 of 122 admissions) [55]. Analysis of the data from the UNOS Registry between 2013 and 2019 demonstrated an abrupt increase in the use of IABP from 7% to 25% of patients undergoing transplant after the policy change [56]. A subsequent quasi-experimental study design of the UNOS registry data had a more balanced temporal representation from 2016 to 2020 and included additional data from 2019 to 2020 post-policy change [56,57]. O'Connell *et al*. [57] found that IABP utilization for hemodynamic support increased by 338% in the two years after the policy implementation, and patients were more likely to receive a transplant with a shorter time to transplant. The widespread availability of IABP, relatively low complication rate, and ease of deployment contributed to its increased usage. Notably, this prioritization has decreased waitlist mortality rates by accelerating transplantation for patients with severe but potentially reversible hemodynamic instability, translating into improved short-term outcomes [4,26].

Impella devices: Impella, a percutaneous ventricular assist device (pVAD), provides greater hemodynamic support than an IABP and has also seen increased prioritization under the new allocation system. A 2023 retrospective study of data from the UNOS registry, spanning from October 2018 to April 2022, in adult patients listed as Status 2, demonstrated an increase in annual Impella use from 8% in 2019 to 19% in 2021 [58]. The authors found that an IABP was more commonly used in patients with advanced age, females, and rare cardiomyopathies (e.g., infiltrative/hypertrophic). At baseline, the Impella group had indicators of higher medical acuity, including mechanical ventilation, dialysis, pulmonary pressure, and a lower success rate of transplantation as Status 2. The Impella group also found a greater increase in BTT on Impella compared to IABP across the United States during the study period; however, this did not necessarily improve waitlist outcomes. The study showed that while there was a wide range of IABP use—the Impella utilization ratio between regions in the United States ranged from 1.77 to 21.31 with higher Impella use in the Southern and Western states—it did not correlate with waitlist mortality nor was the difference explained by medical acuity, regional transplant volume, or waitlist time [58]. Another study, published in 2023, focused solely on the use of the Impella 5.5, which received Food and Drug Administration (FDA) approval in 2019 [59]. A total of 464 patients received Impella 5.5 support during their listing period, with 87% (402 patients) who were ultimately transplanted and 81% (378 patients) who were directly BTT. The authors reported that device complications and failure were uncommon (<5%), and 1-year post-transplant survival was 89.5%. Although less extensively studied compared to IABP and ECMO, Impella utilization has increased similarly due to its robust hemodynamic stabilization capabilities. However, current studies are limited and have yielded mixed results. This device allows patients to maintain sufficient cardiac output while awaiting transplantation, reducing pretransplant mortality among critically ill candidates [3,12].

ECMO (extracorporeal membrane oxygenation): Following the policy change, the most significant change in MCS was observed in ECMO utilization, which increased dramatically from 1.8% to 7% of all heart transplant recipients post-policy [3]. ECMO provides comprehensive cardiorespiratory support for patients with profound hemodynamic compromise and multi-organ dysfunction. Historically, patients bridged on ECMO to heart transplantation have very high post-transplant mortality. Under the new policy, ECMO-supported patients receive the highest transplant priority (Status 1), reflecting their exceedingly high short-term mortality without transplantation. However, there is limited data on the outcomes of patients who are most critically ill. A study on adult patients supported by ECMO at the time of listing who were registered in the UNOS database between November 2015 and September 2019 reported that 296 patients supported by ECMO were listed for transplant, of which 65% (191 patients) were distributed to the old allocation system and 35% (105 patients) to the new 2018 allocation system [36]. The authors found that patients in the new system had a higher cumulative incidence of cardiac transplant and a lower incidence of death or removal from the transplant list compared to patients in the old system. Additionally, the 6-month survival post-transplant rate was 90.6% in the new system compared to 74.6% in the old system. Lastly, the authors found that being listed or transplanted on the new system was independently associated with a shorter waitlist time, improved frequency of transplant, and post-transplant

survival. Moreover, the increased utilization and prioritization of ECMO resulted in significantly reduced waitlist mortality and markedly improved short-term survival outcomes, as these critically ill patients could receive timely transplants, minimizing ECMO-related complications such as bleeding, infection, and multi-organ failure [14,25].

Overall, the approach of the revised policy to MCS device prioritization has successfully achieved its intended objectives: reducing waitlist mortality, shortening transplant wait times, and improving outcomes for critically ill patients. Golbus *et al.* [45] analyzed data from the Scientific Registry of Transplant Recipients (SRTR) database, which included adult patients 18 and older who underwent single-organ heart transplants between January 2017 and January 2020, evaluating trends in tMCS use before and after the October 2018 transplant allocation change. Comparing the old to the new allocation system, the number of patients transplanted with an IABP increased from 7.6% to 28.3%, respectively; meanwhile, those transplanted with pVAD/Impella increased from 1.8% to 4.8%, respectively, and those transplanted with ECMO increased from 0.9% to 5.3%, respectively [45]. Parker *et al.* [47] reported similar trends in the SRTR database for adult heart transplant candidates, with an increase in listings for those on IABP (+4%) and ECMO (+1.2%) and decreased listings for candidates on both low-dose (–18%) and high-dose (–3%) inotropes. An impactful result from the Parker *et al.* [47] study was the increased listings by exception (+12%). The 2018 UNOS allocation change has led to an increase in the use of requests for exceptions, from 3.5% to 15% [26]. While this shift has ushered in a priority of higher acuity patients, it has also introduced unforeseen consequences, including increased exception requests, increased demand for intensive care resources, and potential complications associated with the extended use of temporary support devices, necessitating ongoing assessment of clinical outcomes and resource allocation [4,14].

Continuous Distribution Model

One of the proposals aimed at refining organ allocation more equitably is the development of a continuous distribution model (CDM), a point-based heart allocation system, instead of the current status-based allocation system [60]. The CDM model incorporates multiple patient and donor characteristics through a composite allocation score (CAS) based on five criteria [61].

1. Medical urgency: This factor prioritizes patients based on the severity of their condition, ensuring that those in critical need receive timely transplants. Developing an objective measure for medical urgency poses challenges, such as determining whether to translate existing therapy-based categories into numerical values or to create new multivariable models that accurately reflect urgency without being susceptible to manipulation.

2. Post-transplantation survival: Predicting the post-transplant survival of recipients by matching organs to recipients who will benefit most. Incorporating post-transplant survival into the CAS requires robust modeling to ensure that the predictions are accurate, reproducible, and equitable.

3. Candidate biology: This includes biological factors such as comorbidities, blood group compatibility, and the immune system sensitivity of the recipient. Addressing disparities, such as those faced by patients with blood type O or high sensitization levels, involves adjusting the CAS to provide appropriate priority points, thereby mitigating inherent disadvantages.

4. Geographic proximity: Optimizing transport distances to minimize ischemic times and improve graft outcomes. While proximity efficiency is considered in the CAS, the continuous distribution framework treats distance as a continuous variable, evaluating it alongside other criteria to balance logistical practicality with medical need.

5. Placement efficiency: This aspect focuses on effectively matching donor organs to the most suitable recipients, considering factors such as travel efficiency and minimizing organ wastage.

The transition to a continuous distribution system will be a complex, multi-phase process. Lung and kidney transplantation processes adopted the CAS system, with initial reports showing improvement over the previous system [62,63]. As of August 2022, the Heart Transplantation Committee initiated the development of this framework, progressing through stages such as identifying relevant attributes, building the allocation framework, modeling and analyzing scores, soliciting public comments, and ultimately obtaining board approval. This structured approach ensures that all factors are thoroughly evaluated and that the system is optimized for fairness and efficiency [64].

One significant challenge in this transition is determining the appropriate weight for each attribute within the CAS. For instance, patients with durable LVADs may experience adverse events that affect their survival rates, suggesting that the time spent on an LVAD should have a substantial weight in the CAS. Balancing these weights requires careful consideration to accurately reflect clinical realities and adjust them as necessary [65,66]. The adoption of the continuous distribution model is anticipated to dissolve the rigid boundaries present in the current classification-based system, allowing for a more individualized and equitable approach to organ allocation [67]. As the continuous distribution framework continues to evolve, ongoing modeling and community feedback will be crucial in refining the system. The goal is to create an adaptable allocation model that can swiftly incorporate new scientific insights and respond to emerging challenges in organ transplantation. This dynamic approach holds promise for a more responsive and patient-centered organ allocation system in the future.

Conclusion

The 2018 UNOS heart transplant policy changes have ushered in a new era of organ allocation, leading to significant improvements in patient outcomes and making notable strides toward more equitable access to heart transplantation. The shift from the regional donation service area (DSA)-based allocation system to a 500-mile sharing radius has reduced geographic disparities. The new policy significantly decreased waitlist mortality, especially among high-priority patients, such as those supported by temporary MCS devices, with improved short-term survival and a trend toward better long-term survival rates. The longer procurement distance has increased procurement costs and ischemic times, but with no significant impact on short- or intermediate-term survival rates. Ongoing efforts to optimize preservation techniques and innovative transportation models aim to minimize the effects of ischemia and improve graft viability.

Moving forward, the CDM holds great promise for further refining the allocation system. This model leverages real-time patient data, allowing for more dynamic decision-making based on a CAS that considers factors such as medical urgency, post-transplant survival, candidate biology, geographic proximity, and placement efficiency. The flexibility of the CDM will help to more accurately match donor organs with recipients, optimizing outcomes for both high-risk and stable patients alike.

Despite the advances, challenges remain. For example, the appeals process, which continues to play a significant role in organ allocation, requires further refinement to reduce inconsistencies and ensure equitable access. Monitoring and auditing the appeals process will be crucial to maintain fairness across all transplant centers.

Author Contributions

MQ, AP, KR and MS contributed to the design of review article, written different sections of the review, edited the combined review document to its final format. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

Ethics Approval and Consent to Participate

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Conflict of Interest

The authors declare no conflict of interest.

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