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Impact of mechanical circulatory support on donor heart allocation: past, present, and future.

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Review

Impact of mechanical circulatory support on donor heart allocation: past, present, and future

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The United Network for Organ Sharing (UNOS) recently revised its heart allocation policy to address numerous shortcomings of the previous system. Implemented in 2018, the changes sought to reduce waiting list mortality, clearly define urgency status based on objective physiologic variables, decrease exemption requests, and introduce geographic modifications to ensure organ distribution favors the highest urgency candidates. In large part, UNOS policy revisions were driven by the growing use of continuous flow left ventricular assist devices (CF-LVADs) and the relevant device complications that led to an unacceptably high number of status exemptions. The new 6-tiered system assigns a comparatively lower urgency status to patients supported on CF-LVADs and higher urgency to patients supported on short-term mechanical circulatory assist (MCA) such as extracorporeal membrane oxygenation (ECMO) and intraaortic balloon pump (IABP) counterpulsation. LVAD use as bridge to transplant (BTT) therapy increased steadily throughout the preceding decade due to technological improvements and increased physician familiarity, but the recent policy changes introduce incentives for physicians to withhold this life-saving therapy in order to achieve higher urgency status for their patients. This paper will explore the technological evolution of MCA and the pertinent clinical trials that have led to their FDA approval as BTT and destination therapy. A review of the inception and development of the donor allocation system will be provided before examining available post-policy outcome data. Finally, we will highlight successes and shortcomings of the implemented changes before commenting on areas to potentially expand upon the existing policy.

Keywords

Ventricular assist; Mechanical circulatory assistt; UNOS heart allocation; LVAD; MCA; Destination therapy; Bridge-to-transplant

1. Introduction

End-stage Heart failure is a devastating clinical syndrome whose prevalence and incidence continue to grow. The current global prevalence of heart failure is estimated at 64 million people, accounting for 9.91 million years-lived-with-disability (YLDs) [1]. Although some patients can be managed with pharmacologic therapy alone, cardiac transplant remains the gold standard treatment for patients with persistent symptoms despite optimum medical therapy, with an average survival of 50% at 13 years [2]. However, an insufficient supply of donor hearts persists despite numerous interventions aimed at expanding the available donor pool and has resulted in more time spent on waiting lists and increased attention toward optimizing management strategies for candidates [3]. After results from the REMATCH trial established pulsatile-pump mechanical circulatory assist (MCA) as effective bridge to transplant (BTT) therapy [4], various forms of MCA were developed and used for short-term management of candidates awaiting transplant. However, with the advent of continuous flow pumps, advancements in device durability, and improvements in physician understanding of commercially available technologies, transplant candidates can now be adequately managed for much longer time periods and non-transplant candidates offered MCA as destination therapy [5]. One-year survival for patients supported on third generation left ventricular assist devices (LVADs) is over 80%, and historically devastating complications such as pump thrombosis and pump failure are now scarce events [6].

Device improvements have contributed to a restructuring of the United Network for Organ Sharing (UNOS) allocation system for cardiac grafts [7]. Implemented in October 2018, the changes sought to decrease mortality rates for recipients on the waiting list and introduce additional stratification measures to clearly define the new 6-tiered system and its guidelines. Among other priority changes, the restructuring assigns a higher status to patients supported with extracorporeal membrane oxygenation (ECMO) and nondischargable temporary MCS. Stable patients on continuous flow-left ventricle assist devices (CF-LVAD) are assigned a comparatively lower urgency status, and patients experiencing CF-LVAD complications are required to meet a more rigid set of criteria to attain a higher priority status. Responses to the implemented changes have been mixed, and early clinical data suggest there may be significant costs associated with the new stratification metrics [8]. Teuteberg *et al.* note that the revisions may unfairly limit the availability of allografts to patients supported on CF-LAVD [9], and Cogswell *et al.* have reported that although allocation restructuring may be reducing waiting list mortality as intended, post-transplant outcomes may be worse [10]. Missing from the present lit-

Table 1. NHLBI - National Heart Lung and Blood Institute [2]

1963	First VAD implantation
1969	First TAH implantation
1972	NHLBI initiates an LVAD program
1975	NHLBI sponsors clinical trials of pneumatic LVADs
1991	First implantation of electrical, portable LVAD
1994	First patient discharged from hospital with portable LVAD
2001	REMATCH trial demonstrates superiority of LVAD over optimal medical therapy in New York Heart Association class IV patients

erature is a review of how developments in LVAD technologies have paved the way for organ allocation restructuring and how the implemented priority changes are impacting patients supported on these devices. The goal of this review is to provide a comprehensive overview of how LVAD evolution has shaped changes in organ allocation policy, followed by an examination of new trends and future directions.

2. Ventricular assist: an evolutionary process

The MCA landscape has expanded and improved dramatically since its inception almost 75 years ago (Table 1). In 1953, Dr. John Gibbon used the Gibbon-IBM heart-lung machine to support an 18-year-old patient during repair of an atrial septal defect [11], but it wasn't used until 1963 that Liotta *et al.* reported the successful implantation of an early VAD [12]. The primitive device utilized an intracorporeal pneumatically driven pump using left atrial inflow and thoracic aorta outflow. Several years later De-Bakey successfully implanted a paracorporeal pneumatic LVAD to support a patient suffering from postoperative left ventricular dysfunction [13]. In 1970, the National Heart and Lung Institute implemented a program designed to facilitate VAD development, and in 1978 the first patient was successfully bridged to transplant on ventricular assist [14]. This success paved the way for developing various pulsatile-pump VADs that were large, noisy, and significantly less durable than present devices. Among the earliest LVAD iterations were the Novacor LVAS, Thoratec IVAD, which was among the first devices to receive FDA approval as BTT therapy in December 1995 [15], and HeartMate XVE, which was used in the pivotal REMATCH trial that established a survival advantage for patients with NYHA class IV heart failure treated with LVAD over optimal medical therapy [4].

After the REMATCH trial solidified pulsatile pump VADs as a new long-term myocardial replacement therapy alongside cardiac transplant, efforts were focused on overcoming the limitations of pulsatile volume displacement pumps such as their large size and limited long-term durability. Continuous flow pumps were studied throughout the early 2000's, and numerous technologies became commercially available including DuraHeart LVAD and MicroMed Debakey VAD. However, it wasn't until 2008 when the United States Food and Drug Administration approved HeartMate II for BTT therapy after its pivotal clinical trial [16]. This was a prospective, multicenter study that assessed 133 patients awaiting cardiac transplant who were inotrope-dependent or supported with an intra-aortic balloon pump. Patient survival during the 126 day median treatment period with HeartMate II was 75%, and one year survival was 68%. Patients supported with HeartMate II also experienced superior quality of life and improved functional status compared to their counterparts managed with optimal medical therapy. The following year, Slaughter *et al.* published results of a 2-year, prospective, randomized study comparing the pulsatile-pump HeartMate XVE to the continuous axial-flow pump HeartMate II [17]. The primary study endpoints were survival free from debilitating stroke, reoperation, or device repair. Overall, they reported superior achievement of the primary study endpoint with the HeartMate II, a greater 2-year survival rate, and fewer adverse events compared to HeartMate XVE. The results of this study led to HeartMate II achieving FDA approval as BTT therapy in January 2010 (Table 2). The HeartMate II is a second generation LVAD that uses an axial-flow continuous-flow pump consisting of a rotor suspended in blood by pivot bearings. Fewer moving parts and the continuous mechanism contribute to improved device durability and reduced rates of thrombosis and pump failure compared to the XVE pulsatile pump.

Two years later results published from the Advanced Heart Failure Bridge to Transplant trial led to the FDA approval of HeartWare HVAD as BTT therapy [18]. In this study, Aaronson *et al.* compared results of 144 patients awaiting transplant who were supported with the HVAD continuous flow centrifugal pump to 499 axial-flow pump controls, predominantly HeartMate II. The primary outcome variable was overall survival on the originally implanted device, successful transplantation, or successful explantation to ventricular recovery after six months. Overall, success was achieved in 90.7% of HVAD patients and in 90.1% of controls, establishing noninferiority of HVAD compared to HeartMate II. The primary difference between the centrifugal and axial flow pumps lies in the specific design of the rotating elements. Whereas the axial-flow rotor spins to eject blood in a direction parallel to the rotating elements, the centrifugal-pump rotating elements receive and eject blood tangentially from the blade tips, a mechanism that reduces shear stress, blood trauma, and thrombosis [19].

In 2017, the Clinical Trial to Evaluate the HeartWare Ventricular Assist System (ENDURANCE trial) compared the efficacy of HVAD to HeartMate II as destination therapy [20]. This was a multicenter, randomized trial that com-

Table 2. ***Abbreviation*** **MRS, modified Rankin scale**

Device	Clinical Trial Design	Primary Endpoints	Seminal Publication and FDA Approval
HeartMate II BTT	BTT Patients, no control arm	Survival at 6 mo, noninferiority to expected survival if 65% for BTT patients	2007/2008
HeartMate II DT	Randomization of DT patients 2 : 1 for HeartMate II vs HeartMate XVE	Survival at 2 y, free of disabling stroke (MRS $>$ 3) or device failure	2010
HVAD BTT	Control arm was chosen from INTERMACS registry	Noninferior survival at 6 mo	2012
HVAD DT	Randomization of DT patients in 2 : 1 for HVAD vs HeartMate II	Noninferior survival at 2 y free of disabling stroke (MRS $>$ 4) or device failure	2017
HeartMate 3 BTT	Randomization of both BTT and DT patients in 1 : 1 ratio to HeartMate 3 vs HeartMate II	Noninferior survival at 6 mo free of disabling stroke (MRS $>$ 3) or device failure	2017
HeartMate 3 DT	Nested within the same trial as the BTT study	Noninferior survival at 2 y free of disabling stroke (MRS $>$ 3) or device failure	2018

Despite meeting the primary noninferiority endpoint, there was a concern for a higher incidence of stroke in the HVAD group. As a result, the FDA mandated a supplemental trial that tested efficacy of tight blood pressure control to reduce the incidence of strokes with HVAD. Based on a combination of data from the original and supplemental trial, the device was then FDA approved for DT[2].

pared results of 297 patients treated with HVAD to 148 controls supported with HeartMate II, all of whom were ineligible for transplant. The primary endpoint was survival at two years free from debilitating stroke or device removal due to malfunction or failure. The success rates for the two groups were 55.4% and 59.1%, respectively, with a greater percentage of controls requiring device replacement (16.2% vs 8.8%) and a greater percentage of HVAD patients experiencing a stroke (29.6% vs 12.1%). Subsequent analysis of the ENDURANCE trial identified several variables that could potentially account for the HVAD stroke association. These included discrepancies in antiplatelet therapy dosing, pump design differences, and lower international normalized ratios (INR) in the study group [21]. The variable that received the most attention, however, was elevated mean arterial pressure (MAP), which was identified as a highly statistically significant independent risk factor for stroke events in the trial. This led to the FDA-mandated ENDURANCE supplemental trial, designed to evaluate the effect of intense blood pressure control on stroke reduction after one year of HVAD therapy. Results showed that patients with a MAP below 85 mmHg experienced a non-significant reduction in stroke rates after one year compared to results from the original trial (22.3% to 16.9%) [22]. Data published in the supplemental trial combined with original data led to HVAD achieving FDA approval in 2017 as destination therapy for patients who were ineligible for cardiac transplant.

Later in 2017, results from the MOMENTUM 3 trial comparing HeartMate III to HeartMate II were published. HeartMate III was a new, fully magnetically levitated centrifugal continuous flow pump engineered to carry a lower risk for pump thrombosis than the traditional axial-flow pump in HeartMate II [23]. 152 patients supported with HeartMate III were compared to 142 treated with HeartMate II, and the primary outcome of interest was a composite of survival free of disabling stroke at one, three, and six months. The primary endpoint was achieved in 86.2% in the HeartMate III group and in 76.8% of the HeartMate II group. There were no significant differences between HM II and HM III in overall mortality (13.1% vs 15.5%) or rates of disabling stroke (5.9% vs 3.9%), but reoperation due to pump malfunction occurred more frequently in the HeartMate II group (14.3% vs 2.7%). Additionally, no patients in the HeartMate III group experienced pump thrombosis compared to 14 patients (10.1%) in the HeartMate II group. This led to the device's FDA approval as BTT therapy in 2017 and as destination therapy in October 2018.

3. Donor allocation: a historical perspective

The allocation of donor hearts inevitably requires the distribution of a highly coveted and finite resource to candidates who meet a rather narrow set of selection criteria. The fundamental goal of organ allocation policies has always been to produce methods that allow for equitable access to available organs while maximizing the overall value of the transplant [24]. In the 1980's, the Organ Procurement and Transplantation Network (OPTN) assembled a consortium of cardiologists and cardiothoracic surgeons called the Heart Transplant Committee which would become the Thoracic Organ Transplantation Committee. The committee's stated objectives were to design and monitor thoracic organ allocation policies and to address issues related to procurement and transplantation. Among the committee's first actions was the approval of a primary allocation algorithm which utilized a two-tiered system for medical urgency, status 1 and status 2. Patients were classified as status 1 if admitted to the ICU and requiring inotropic support or receiving mechanical circulatory assist, including support with ventricular assist, TAH, or IABP. Status 2 included all other transplant candidates, including those suffering from refractory angina, congenital heart disease, refractory ventricular tachycardia, and various restrictive cardiomyopathies [8]. Candidates supported on VADs were assigned status 1 priority due to the poor durability and

high complication rates of the available devices which included thromboembolism, mechanical pump failure, and infection [25]. This policy remained in effect for the following decade despite criticism that it excluded critically ill adult patients from status 1 designation, including patients for whom MCA was contraindicated and those with life-threatening arrythmias [26]. In 1999, the OPTN instituted a major policy change that stratified status 1 patients into distinct tiers, 1A and 1B. The 1A classification required patients to either be admitted to the transplant center or to have experienced a VAD complication within the previous 30 days. Patients supported by ventricular assist for 30 days without complication and those requiring inotropes were designated 1B. However, all patients supported on ventricular assist were assigned 1A status for a 30-day period immediately upon device implantation, irrespective of hemodynamic stability or candidacy for a different intervention. Among other priorities, the policy change reflected the needs of patients suffering from high LVAD complication rates and permitted candidates supported by MCA the opportunity to achieve highest priority status. The enacted policy reduced median waiting times for 1A and 1B designated patients compared to pre-policy status 1 patients, and it reduced overall waiting list mortality [27]. In 2002, the policy requiring VAD patients to accrue status 1A time immediately upon device implantation was dissolved, allowing patients to be listed as 1A during any 30-day period following VAD implantation. Patients were also not required to be hospitalized to maintain 1A status designation, allowing for medical optimization prior to achieving 1A status.

Between 2006 and 2015 the number of cardiac transplants increased almost 3-fold and the percentage of patients supported with durable VADs increased from 16% to 36% [28]. In 2018, The United Network of Organ Sharing (UNOS) made significant revisions to the heart allocation policy in the United States. Designed to reduce waiting list mortality, the newly implemented 6-tier system (statuses 1-6) introduced additional categories to more clearly define the urgency status of candidates and address perceived shortcomings of the previous 3-tiered system [8]. Specifically, the modifications sought to correct the following: an excessive number of candidates within 1A suffering from a broad spectrum of urgency needs, inconsistencies in the geographic sharing scheme, and, crucially, a lack of accounting for the increasing use and durability of MCS devices and relevant complications.

Prior to the implemented changes, patients in cardiogenic shock supported with ECMO and stable patients experiencing ventricular assist complications were all assigned 1A status and competed equally for organs. This led to concern for overcrowding within the highest urgency status and perceived inequities in organ allocation. Some of the strongest evidence given in support of the policy change was the significant variance in six month waiting list mortality rates among different status 1A candidates: 4.8% among patients with MCS infection, 5.1% for candidates supported on ventricular assist for 30 days, and 35.7% for those supported on ECMO. Patients supported on mechanical ventilation and ECMO experienced the highest waiting list mortality among status 1A candidates, and VAD-supported candidates utilizing their discretionary 30-day status and those with infections had the lowest waiting list mortalities [29]. Other candidates poorly served by the previous system included patients with congenital heart disease and patients intolerant of inotropic medication or suffering from potentially fatal arrythmias: between 2009 and 2011, these candidates together comprised nearly all of the 605 status 1A exemptions that were submitted, with over 90% receiving approval.

In response, the allocation system was redesigned to stratify previously status 1A patients into three tiers (1, 2 and 3) with different urgency statuses (Table 3). Candidates assigned the highest priority status were those in cardiogenic shock and supported with ECMO or another biventricular non-dischargeable MCS, as well as those supported on MCS with a life-threatening arrythmia. Patients supported on LVAD, IABP, MCA with device malfunction, and those with potentially fatal ventricular arrythmias not requiring MCA were all assigned status 2. Patients supported with LVAD and using their discretionary 30 days were assigned status 3, along with those experiencing device infection, pump thrombosis, and hemolysis. This status 2 and 3 designations for various patient populations on LVAD therapy reflect the technical and clinical improvements made to devices and the perception that patients supported on them have less urgent needs than previously. They were also driven by the expanding use of LVADs and the device complications that resulted in an excessive number of high priority status exemptions. Studies analyzing early results of the allocation change shed light on the clinical impact already made and provide information about the changing landscape to guide physicians and inform patients.

4. Clinical outcomes

The OPTN recently published results of the impact the new policy has had on the types of mechanical device support used, waiting list mortality, and post-transplant survival [30]. They report an overall increase in patients supported with short-term MCA therapies such as ECMO (3.7% to 6.5%) and IABP (12% to 27%) and a decrease in LVAD use (79% to 61%). These results are consistent with those reported by Cogswell *et al.* who observed a significant decrease in the patients bridged to transplant on LVAD therapy, a 4-fold increase in transplant recipients supported by ECMO, and overall longer ischemic time (3.0 to 3.4 hours) [10]. The OPTN report found that the number of deaths per 100 patient years was highest in Status 1, followed by Status 2 then Status 3, which was interpreted as indicative of the policy's improvements in risk-stratifying candidates. This observation was also made by Goff *et al.*, who compared transplant characteristics and early outcomes between the old and new systems [8]. They found a 10% increase (68% to 78%) in transplants given to the

Table 3. 2006 transplant status with corresponding 2018 status. The duration of listing varies by indication [39]

Status 2006	Status 2018	Indications
1A	1	• ECMO[1] • Non-dischargeable Ventricular Assist Device[2] • MVS with life threatening arrhythmia[2]
	2	• Non-dischargeable LVAD[2] • Intraaortic Balloon Pump[2] • Dischargeable TAH/RVAD/BiVAD[2] • Mechanical circulatory support with mechanical failure[2] • VF/VT without mechanical circulatory support[2]
	3	• Dischargeable LVAD[3] • High Dose inotrope/ multiple inotropes requiring monitoring[2] • ECMO[4] • Non-dischargeable LVAD[5] • Intraaortic Balloon Pump[5] • Percutaneous Endovascular LVAD[5] • Mechanical Circulatory Support with Right Ventricular failure[2], infection[6], aortic insufficiency[8], mucosal bleeding[7], hemolysis[2], and pump thrombosis[2]
1B	4	• Hypertrophic cardiomyopathy[8] • Restrictive cardiomyopathy[8] • Dischargeable LVAD[8] • Inotropes without monitoring[8] • Intractable angina[8] • Congenital heart disease[8] • Re-transplant[8]
	5	• Multiple organ transplant[9]
2	6	• All others[9]

[1] Renewable every 7 days
[2] Renewable every 14 days
[3] Discretionary 30-day period
[4] If status 1 is not renewed
[5] If status 2 is not renewed
[6] 14 days if clinical evidence of driveline infection, 42 days if bacteremia requiring antibiotic, 90 days if device pocket infection or recurrent bacteremia
[7] 14 days if two hospitalizations in 6 months, 90 days if 3 times in past 6 months
[8] Renewable every 90 days
[9] 180 days

highest urgency patients (previously status 1A and presently statuses 1-3) and reported that six-month post-transplant patient survival was not significantly different between the two eras (93.6% pre and 92.8% post). Although no difference was observed for waiting list mortality between the two groups (14.8 pre to 14.9 post deaths per-100 patient years), waiting list mortality for status 1 candidates aligned with Scientific Registry of Transplant Recipients (SRTR) modeling and was significantly higher than lower status candidates (statuses 2-6). The higher waiting list mortality observed in the greatest urgency status was interpreted as clinically meaningful evidence of improved stratification with the new system, a finding consistent with the OPTN report.

The OPTN report also found that 77% of post-policy transplant recipients were distributed between status 1 (8%), status 2 (46%), and status 3 (23%), as opposed to 68% of pre-policy transplants occurring in 1A and 28% in 1B. They observed no change in one-year waiting list mortality or six-month graft survival, results that differ from those reported by Cogswell *et al.*, who found that 90-day and 180-day survival estimates were lower in the new system compared to the old (87.5% and 94.5%; 77.9% and 93.4%). Cogswell *et al.* also reported that six-month waiting list survival was higher in the new system compared to the previous (96.1% to 95.0%) but concluded that the modest reduction in waiting list mortality likely does not compensate for the observed worse outcomes, especially considering the waiting list mortality in the previous system was already low.

The new policy does not appear to reduce exemptions, nor does it address the incentive for physicians to initiate or withhold LVAD therapy to achieve a higher urgency for patients. UNOS proposed that the introduction of additional stratification metrics and more clearly defined hemodynamic listing requirements would reduce the number of exemption requests but likely lead to an overuse of high-priority support therapies like ECMO and IABP. Results from Parker *et al.* are consistent with fears of short-term therapy overuse but suggest the policy change may actually be increasing exemptions, particularly within the status 2 group [31]. Their analysis compares baseline characteristics and clinical outcomes of pre and post-policy cohorts and demonstrates a significant increase in patients supported on IABP (4.5% to 8.2%) and ECMO (1.2% to 2.6%), and a decrease in LVAD therapy (27% to 24%). Exemptions increased significantly (3.5% to 15%) and both low-dose and high-dose inotrope therapy declined (23% to 5.6% : 8.8% to 5.8%).

5. Present challenges and future research

These reports raise interesting and complex issues about the paradigm shift taking place as a result of the allocation restructuring. The decline in patients supported with durable LVAD and rise in ECMO and IABP use suggest clinical decision making may be prioritizing status urgency at the expense of medical optimization. Patients who may be best served with LVAD therapy could be discouraged or prohibited from therapeutic options because of the comparatively lower urgency status it confers, and a disproportionately large number of patients offered higher-urgency temporary therapies such as ECMO. This trend forces patients to compete for organs based on clinical deterioration and creates incentives for physicians to withhold potentially life-saving treatment, a scenario akin to withholding dialysis treatment for a renal transplant candidate in clinical decline to optimize the candidate's likelihood of being matched to a donor [32]. In this scenario, the "life-boat" problem acknowledged with the previous system [33] will continue to burden transplant centers with more high-urgency candidates who are not being optimally managed, worsening patient outcomes and organ survival.

The policy changes also appear to be having early and profound effects on median time spent on transplant waiting lists and on the number of patients listed and delisted for transplantation. Although median waitlist times appear to be decreasing among the highest urgency candidates, preoperative hospital stays may be increasing, leading to a resource shift toward intensive inpatient management strategies that can be costly for transplant centers and fail to serve the best interests of patients [34]. Whether or not the policy changes are impacting the total number of patients listed for transplant remains unanswered, but considering the observed trends to date, it appears likely that total listing will rise alongside increases in use of MCS devices that confer a higher priority status such IABP and ECMO.

The new allocation system also fails to sufficiently address multiorgan transplant; patients receiving simultaneous heart and kidney transplants experience a significantly higher waiting list mortality compared to heart transplantation alone, and the new policy does not address the urgency needs of this patient population [35]. Assigning status 1 designation to multiorgan transplant candidates would theoretically reduce the multiorgan waiting list mortality without introducing significant costs on the lifeboat. Amendments to the newest allocation system will also need to address the effect of therapeutic provider discretion on patient chances of receiving a transplantation. Lung allocation score (LAS) and Model for end-stage liver disease (MELD) score have proved invaluable tools for stratifying lung and liver transplant candidates [36, 37], respectively, but attempts to create a similar objective set of criteria for cardiac transplantation have either proved to be ineffective or have failed to address patients supported on MCS. Creating a comprehensive and valid patient stratification tool is a crucial step toward improving allocation policies and optimizing the net benefit of every donor. Although extensive research has been undertaken to identify negative predictors of long-term graft function and patient quality of life [38], these findings have failed to translate into an effective set of patient stratification metrics. Lastly, the regional variation in donor availability and disparate waiting list time for candidates in different geographic regions remain poorly understood and insufficiently addressed by the implemented changes, limiting the conclusions that can be drawn from available studies.

6. Conclusions

Improvements in device design and durability have led to an increasing number of cardiac transplant candidates being managed with some form of MCA, in particular LVADs. In large part, the reorganization of UNOS allocation criteria was driven by the growing number of candidates bridged to transplant on continuous-flow LVADs. The lower urgency status assigned to patients supported by LVAD compared to ECMO has resulted in a smaller percentage of LVAD patients ultimately bridged to transplant and a substantial increase in ECMO-supported patients who receive donor grafts. Consistent with its intended goals, the policy shift has introduced additional stratification metrics to prioritize the highest urgency patients and more clearly defined guide listing criteria. To date there has not been a significant reduction in waiting list mortality, although this goal may ultimately be achieved as more time passes since initial policy implementation. Although the total volume of cardiac transplants has remained the same since allocation restructuring, there may be more patients being placed on devices that afford them higher priority status. Understanding the full effect of the policy change on long-term graft performance and overall mortality will require a longer period of observation and additional research investments. Nevertheless, it is clear that allocation priority policy changes have a substantial impact on patients sup-

ported with continuous-flow LVADs, and patients can expect additional policy changes as the commercially available device landscape expands and improves.

Author contributions

All persons who meet authorship criteria are listed as authors. Each author certifies that he or she has participated sufficiently in the work to take public responsibility for the content, including content design, analysis, writing, and revisions.

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All persons who made significant contributions to the manuscript but who do not meet criteria for authorship would be listed here. Because we have not received substantial contributions from non-authors, none are listed.

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Conflict of interest

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