



Policy and Oversight of Cardiac Transplantation

REVIEW

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ABSTRACT

The first heart transplantation in the United States was performed in 1968. The first national heart allocation system was developed two decades later in 1988 as a two-tiered system. Our current heart allocation system, adopted in 2018 as a six-tiered system, is evolving to become a continuous distribution model. Herein, we review the history of the Organ Procurement and Transplantation Network, the evolution of the cardiac allocation system, modern day challenges of the current heart allocation system policy, and the future of transplantation given ongoing implementation of the modernization initiative.

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HISTORY OF ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

In 1954, the kidney became the first successfully transplanted human organ.¹ In 1968, the first heart transplantation was performed in the United States (US).² These early transplants were managed by individual transplant hospitals, while organ procurement organizations (OPO) managed all aspects of organ allocation. If an organ could not be used at a hospital local to a donor, there was no national matching to assist other candidates in need of transplantation. As a result, many organs could not be utilized simply because a compatible recipient could not be located in a short period of time. In 1977, the Southeast Organ Procurement Foundation (SEOPF) initiated the first computer-based organ matching system, titled “United Network for Organ Sharing” (UNOS).³ By 1982, the SEOPF established the first kidney matching center for 24/7 assistance in placing organs.³

Landmark milestones in 1984 paved the way for national transplant policies. First, the National Organ Transplant Act established the foundation for a national organ recovery and allocation system with the private sector. The goal of this system was to ensure that allocation would be carried out in a fair, efficient, and equitable way. Additionally, UNOS separated from SEOPF as a nonprofit organization. Two years later, UNOS received the first federal contract to operate the Organ Procurement and Transplantation Network (OPTN), and the national heart transplant allocation system was formed.³ In 2000, the OPTN’s “Final Rule” defined requirements for allocation policies that included sound medical judgment, best use of organs, and the ability for centers to decide whether to accept an organ offer to avoid wasting organs and to promote efficiency.⁴ The Final Rule also includes a requirement that policies “shall not be based on the candidate’s place of residence or place of listing, except to the extent required by the other requirements of the rule.” With guidance to fulfill the requirements of the Final Rule, UNOS created and continues to optimize electronic data collection methods and organ allocation processes, some of which are used to this day (Table 1).

HISTORY OF CARDIAC ALLOCATION SYSTEM

Amongst the listed goals of the OPTN is to “have a system to allocate donated organs equitably among transplant recipients according to the established medical criteria.”⁵ With this goal in mind, the first heart transplant allocation developed in 1988 was a two-tiered system based on medical urgency (Table 2). The two statuses were based on the need for hospitalization for inotropic agents, mechanical ventilation, monitoring needed in the intensive care unit, or utilization of temporary or durable mechanical circulatory support. Incorporation of distance allowed for geographic allocation based on proximity, with donor hearts being offered first to all candidates within the local donor service area, then sequentially to zones defined by nautical distance from the donor hospital (zone A: within 500 nautical miles; zone B: 500–1,000 nautical miles; and zone C: > 1,000 nautical miles).

Over time this system demonstrated poor differentiation of medical urgencies between the two tiers. Additionally, left ventricular assist device (LVAD) technology reached prime time. Thus in 1999, the heart allocation system expanded from its two-tiered (Status 1 and 2) system to a three-tiered system (Status 1A, 1B, and 2). Similar to Status 1 patients in the 1988 heart allocation system, the new Status 1A patients were required to be admitted to the transplanting hospital and to be supported with temporary mechanical circulatory support (tMCS), mechanical ventilation, or inotropic agents with continuous hemodynamic monitoring. Durable LVAD patients also received 30 days of guaranteed Status 1A time and were eligible for 1A Status with evidence of device complications (infection, thromboembolism, ventricular arrhythmias, or device mechanical failure). Status 1B patients were now supported with durable LVADs or continuous infusion of inotropic agents without invasive hemodynamic monitoring. Status 2 patients included all other listed patients who did not meet the above criteria (Table 2).

The intention of creating a three-tiered system was to improve waitlist mortality and waitlist time.⁶ However,

YEAR	TECHNOLOGICAL INNOVATION
1992	UNOS prepares first-ever comprehensive report on transplant survival rates for all active hospitals in the United States.
1996	UNOS creates the first Transplant Information Electronic Data Interchange (TIEDI) eliminating the step of mailing paper forms to the OPTN.
1999	UNOS launches UNet, the first internet-based transplant information database system for all organ matching and management of transplant data.
2006	UNOS launches DonorNet, a secure, internet-based system in which organ procurement coordinators send out offers of newly donated organs to transplant hospitals with potential candidates.

Table 1 United Network for Sharing Technological Advancements (UNOS) list of technological innovations.

1988 ALLOCATION	1999 ALLOCATION	2018-PRESENT ALLOCATION	CANDIDACY
Status 1	Status 1A	Status 1	Extracorporeal membrane oxygenation Nondischargeable surgically implanted ventricular assist device Durable LVAD with life-threatening arrhythmias
Status 1	Status 1A	Status 2	Durable LVAD with device failure IABP Percutaneous endovascular LVAD Surgically implanted nonendovascular LVAD Dischargeable BiVAD/RVAD/total artificial heart Sustained ventricular arrhythmias
Status 1	Status 1A	Status 3	Durable LVAD (30-day discretionary period) Inotropic agents with continuous hemodynamic monitoring Durable LVAD with complications
Status 1	Status 1B	Status 4	Durable LVAD without complications Continuous inotropic agents without hemodynamic monitoring Congenital, hypertrophic, restrictive, amyloid, cardiomyopathies* Intractable angina* Retransplants*
Status 2	Status 2	Status 5	Dual-organ transplants*
Status 2	Status 2	Status 6	All other listed candidates

Table 2 Heart allocation system since 1988. BiVAD: biventricular assist device; IABP: intra-aortic balloon pump; LVAD: left ventricular assist device; RVAD: right ventricular assist device. * Clinical scenario described and risk-stratified in the 2018 allocation system but not specifically included in prior allocation systems.

with continued improvement in LVAD technology, similar problems that necessitated the development of a three-tiered system now required further differentiation. The growth of patients in Status 1A or 1B exploded from 42% in 2000 to 72% in 2015.⁷ The median waitlist time for Status 1A ballooned to 87 days, despite the initial goal of capturing patients with expected mortality less than 7 days.⁸ Ergo a six-tiered heart allocation system appeared in 2018 based on medical urgency, further subcategorizing Status 1A into Status 1, 2, 3, prioritizing those on surgical and nonsurgical nondischargeable mechanical devices. Further details are described in [Table 2](#). Additionally, this new heart allocation system revised the geographic sharing to ensure broader availability of donor hearts to the sickest patients by eliminating donor service areas, now using only strict nautical mile boundaries.

The current process in the US to allocate deceased donor organs occurs with these steps: the match system eliminates candidates who cannot accept the deceased donor organ based on size, blood type, and willingness of center to accept certain risk markers (eg, hepatitis C virus), then ranks the remaining candidates in a donor sequence of complex rules based on the “Final Rule,” with guidance from organ-specific committees. OPOs must first offer organs to potential recipients in this order and may only go outside this order when options have been exhausted or if time does not permit.⁹

PROS AND CONS OF CURRENT ALLOCATION POLICY

The intention of any heart allocation policy change is to decrease median waitlist time and waitlist mortality.⁶ As a community, we accomplished this objective and much more. Waitlist mortality improved with every allocation system, decreasing from 24.4% to 17.2% and now down to 7.4%.¹⁰ Furthermore, the current allocation system accounts for the highest percentage of heart transplants completed from the listed heart transplant candidates, increasing from 61.1% between 1988 and 1998 (21,850/35,778) to 67.4% between 1999 and 2018 (41,020/60,830) to 71.6% between 2018 and 2023 (15,172/21,187) in the current allocation system.¹⁰ Lastly, post-transplant 1-year survival is at an all-time high, rising from 84.4% in the original allocation system to 89% in the 1999 heart allocation system to today, an impressive 91.4%.¹⁰ Despite these accomplishments, certain concerns persist ([Table 3](#)).^{11,12}

Due to a wider donor pool available in the current allocation system and utilization of innovative technologies, a nearly 40% increase in miles traveled for procurement is associated with near doubling of transplant costs, from \$6,812.07 to \$12,383.¹³ This current range is likely an underestimate, and further cost analysis is needed as technology advances and more expensive devices are being used to push the boundaries of transplantation.

PROS	CONS	UNDETERMINED
Increase in number of transplants	Increase in costs	Increase in temporary mechanical circulatory support
Increase in post-transplant 1-year survival	Increase in exception request utilization	Decrease in durable left ventricular assist devices
Decrease in waitlist mortality	Increase in ischemic times	Decrease in inotrope usage
Long-term survival		Increase in distance traveled

Table 3 Current pros and cons of the 2018 heart allocation system.

Only time will tell if these costs are sustainable among the transplant community, the OPTN, and patients.

The current allocation system also does not allow for discrimination between patients needing tMCS or inotropic support. Treatment strategy rather than medical severity dictates status listing. A decision to insert a tMCS, utilize an inotropic agent, or implant a durable LVAD in a patient that may benefit from all three becomes tainted by resultant listing status. While each of these options may be an appropriate and safe option, the policy has resulted in a sharp rise in tMCS devices exploding Status 1 and 2 listings, while use of inotropic support or durable LVADs as Status 4 has plummeted.^{12,14} More importantly, these changes were seen only in US-based transplant centers immediately following the heart allocation system in 2018 and not seen in Canada or nontransplant US centers.¹⁵ Long-term studies are needed to compare and evaluate morbidity and mortality impacts of choosing one strategy over another.

The 1999 heart allocation system added exception requests for patients who did not qualify for Status 1A or 1B based on traditional criteria and the creation of Regional Review Boards to monitor patient status selection by transplanting centers, which continued in the 2018 heart allocation system. Currently, 95% of exception requests are approved, irrespective of region. While the rationale for requesting an exception request would be to address inequities in the current allocation with respect to patient factors (blood type, multiple organ, level of sensitization, underrecognized medical urgency, etc) and complications of treatment options (arrhythmias with inotropic agents, complications with mechanical circulatory support, etc), the magnitude of requests implies provider preferences of treatment option is playing a role. Nearly 40% of all transplant patients listed in Status 2 are listed by exception, and nearly 600 exception requests are now being submitted every month.^{16–18}

In the future, UNOS policy and data collection need to evolve to allow for more in-depth analysis of these exception requests and to more rapidly develop policy changes to accommodate and mitigate exceptions more appropriately. Currently, the Heart Committee of OPTN evaluated this overcrowding in the current allocation system and created an interim policy that would require failure of inotropic therapy prior to qualifying for a higher status with tMCS.¹⁹ This policy was approved by the board

in December 2023. The average time from policy approval to implementation has historically varied from 4 to 18 months depending on the complexity and urgency of the new policy. The original estimate on this policy was implementation by December 2024. However, OPTN halted all work on pending policy updates in fall of 2024 while they continued work on modernization efforts. Only recently has the work on this policy been reopened, and so far no implementation date has been released.

MOVING TOWARDS CONTINUOUS DISTRIBUTION

In December of 2018, OPTN approved the continuous distribution (CD) framework for all allocation of organs. In 2022, the Heart Committee began developing this framework for hearts. The intent of CD is to rank waiting list candidates on points for various factors simultaneously—such as medical urgency, patient access, and candidate biology among other attributes—promoting a more equitable approach to matching heart donors and candidates.²⁰ This would eliminate the current 2018 six-tiered heart allocation system and convert it into a continuous rating scale. Some factors currently not included in the allocation, such as waiting time on durable LVADs, blood type, and sensitization based on number of unacceptable antigens listed by a program, will be incorporated. OPTN asked the transplant community via public comment in a values prioritization exercise (VPE) to rank attributes against one another, thus weighing the relative importance of each attribute to formulate a composite allocation score (CAS). The sum of the weights of all attributes would add up to 100%, are derived from the value-based decisions, and align with the requirements found in the National Organ Transplant Act and the OPTN Final Rule. A higher CAS places a patient closer to the top of a match run.

The results of the 2024 VPE were not surprising. The overall weights valued the following characteristics in the following order: medical urgency (37.4%), pediatric candidate (23.7%), prior living donor of other organs (14.1%), biologically difficult to match candidate (10.8%), candidate with good post-transplant outcomes (6.2%), candidate who has waited a long time (4.6%), and very nearby candidate (3.2%).²⁰ These

VPE results are advisory, and ultimately the responsibility of policy development resides with the Heart Committee. Under the current policy, post-transplant survival will unlikely be included in the CAS until more longitudinal data is available. Other factors that are likely to be included in the first CD CAS are shown in [Table 4](#). The heart transplantation committee projects to have a proposal completed by December of 2025, with the goal of implementing CD by 2027.

OPTN MODERNIZATION

The relationship between OPTN, the Health Resources and Services Administration (HRSA), which is a branch of the US

Department of Health and Human Services, and Centers for Medicare and Medicaid Services (CMS) is dynamic and complex, but all have some oversight and regulatory aspects to ensure safe transplant practices ([Table 5](#)).^{9,21}

In March 2023, HRSA launched the OPTN modernization initiative to better serve the needs of patients and families. It aimed to strengthen accountability, equity, and performance in the organ donation and transplantation system through a focus on five key areas: technology, data transparency, quality improvement and innovation, governance, and operations ([Table 6](#)).²²

This new legislation gave HRSA the authority to create an independent board of directors to facilitate transparent, accountable OPTN governance (with oversight from HRSA).

	MEDICAL URGENCY	REDUCING BIOLOGICAL DISADVANTAGES	PATIENT ACCESS	PLACEMENT EFFICIENCY
Potential attributes	Adult status Pediatric status Waiting time on durable LVAD	Blood type Sensitization	Waiting time Priority for pediatric candidates Priority for prior living donors	Distance between transplant and donor hospital
Goal	Prioritize sickest candidates reducing wait list mortality	Increase transplant opportunities for those who are medically harder to match	Promote appropriate transplant access for all candidates	Consider resource requirements needed to match, transplant and transplant an organ

Table 4 Attributes under consideration by the Heart Transplant Committee for the first Continuous Distribution Composite Allocation Score.

ORGANIZATION	ROLE
OPTN	Maintain an equitable organ allocation for patients on the national waitlist governed by the National Organ Transplant Act and the Final Rule. They can include changes to allocation policy, bylaws, data collection, member requirements, guidance documents, and patient education materials. OPTN committees initiate all projects.
HRSA	Award contracts to operate and oversee the contractors for OPTN and SRTR. SRTR conducts advanced statistical analysis of OPTN data. HRSA's Final Rule also requires the Secretary of Health and Human Services to approve proposed policies prior to implementation that the OPTN Board recommends be enforceable.
CMS	Certifies and regulates OPOs, evaluates OPTN member standing of transplant programs, requires donor hospitals to report to OPOs patient-level data of transplanted individuals who have died in the hospital, and regulates all laboratory testing including histocompatibility laboratories. CMS can decertify OPOs and suspend payments/reimbursements of transplant programs and histocompatibility laboratories if they do not comply with established requirements.

Table 5 Roles of three organizations in transplantation. CMS: Centers for Medicare and Medicaid Services; HRSA: Health Resources and Services Administration; OPTN: Organ Procurement and Transplantation Network; SRTR: Scientific Registry of Transplant Recipients; OPOs: organ procurement organizations

Technology	Continual focus is on improved IT system functionality and security while ensuring continuity of services and protecting patient safety.
Data Transparency and Analytics	The modernization process provides easily accessible, high-quality and timely data to make informed patient, donor, and clinical decisions. It also measures and evaluates program performance and helps inform oversight and compliance activities.
Quality Improvement and Innovation	The OPTN promotes a culture of quality improvement and innovation across the network by leveraging timely data and performance feedback, collaborative learning, and strategic partnerships.
Governance	The OPTN Board of directors is high-functioning and has greater independence. It also represents diversity of communities and delivers effective policy development.
Operations	The OPTN is effective and accountable in its implementation of organ policy, patient safety, compliance monitoring, organ transport, OPTN member support, and education of patients, families, and the public.

Table 6 Organ Procurement and Transplantation Network modernization aims.

In addition, HRSA issued multi-vendor contract solicitations in September 2024 to support broad competition and best in class vendors for critical OPTN functions (Table 7).²³ The hope of these changes is to produce better outcomes for patients through specialization, expertise, and focus while ensuring greater accountability. Separation of the OPTN board of directors from the OPTN contractor is a key step in HRSA's commitment to prevent conflicts of interest within the network. HRSA has awarded the American Institutes for Research the OPTN Board Support Contract to organize

a special election for a new OPTN Board of Directors. The US Congress has enacted \$67 million in funding for HRSA to implement the OPTN Modernization initiative for the fiscal year 2025, which is a \$13 million increase from the fiscal year 2024.²⁴

While laudable, concern is growing in the transplant community regarding the potential negative impact of this process, particularly with the special election for the OPTN Board of Directors (Table 8).²⁵ Frustrations regarding lack of transparency in the board selection process, pressured

GOAL	COMPANY AWARDED	VISION
Improving patient safety	Arbor Research Collaborative for Health	Will address patient safety and the policy compliance systems and processes to improve oversight of the multiple entities in the OPTN.
Supporting OPTN IT modernization	General Dynamics Information Technology Inc	Will focus on opportunities to improve the OPTN organ matching IT system and inform HRSA's Next Generation IT procurement and development.
Increasing transparency and public engagement in OPTN policy development	Maximus Federal Services	Will provide advance opportunities to improve public visibility and engagement in the OPTN policy-making process.
Strengthening patient-centered communications	Deloitte Consulting	Will focus on improvements in communications from the OPTN, within the OPTN, and patients/families.
Improving OPTN financial management	Guidehouse Digital	Will address improvements for OPTN's budget development and management systems and processes.
Improving organ transplantation logistics and transportation	MITRE	Will work to develop system requirements to improve how organs are transported safely including how to ensure trackability during transport.
Evaluating organ allocation policy	MITRE	Will work to develop an evaluation framework to assist HRSA in assessing organ allocation policy effectiveness.
Program management, data partnerships and analysis	Summome	Will provide comprehensive program management support and work with HRSA to coordinate multi-vendor OPTN activities and performance.

Table 7 HRSA-OPTN modernization contracts and goals to date. HRSA: Health Resources and Services Administration, OPTN: Organ Procurement and Transplantation Network

CONCERN	REASONING
Who are the nominating committee members?	Representation of stakeholders on the OPTN Board needs to be determined by a Nominating Committee that has earned the respect and trust of the transplant community. Importantly, the Nominating Committee needs to include individuals with experience and expertise in organ acquisition and transplantation that is necessary to assess the qualifications of potential nominees.
Will there be political influence in decision making?	The OPTN was established as a public-private partnership to ensure that highly sensitive policy decisions related to patient access, safety, and quality are made by the clinical and patient communities, independent of political influence. There is growing concern that decisions from the board may impact different regions differently and therefore become politically influenced or sensitive as the nominating committee is chosen through a closed process by government officials subject to political pressure.
Does the process of a nominating committee violate NOTA and Final Rule?	The OPTN Board and Executive Committee have requested HRSA verify the legality of HRSA's special election process as there are concerns that this process is not consistent with NOTA and the Final Rule.
By eliminating current or recent board members from the OPTN Board, are we setting up the system for success or failure?	The limited Nominating Committee and Board selection criteria made public by HRSA indicates that anyone who served on the OPTN Board during the past 10 years will not be considered, based on "conflict of interest." Ten years seems to be arbitrary, and this may leave the Board of Directors without any understanding of institutional history and expertise.
Why is there a lack of transparency, communication, and opportunities for change with constructive feedback from patients, societies, and OPTN?	To date, an overall sentiment is that HRSA has not involved structured opportunities for input from key stakeholders. This lack of engagement can create a disconnect between decision-makers and the operational realities faced by those in the field.

Table 8 Concerns raised by the American Society of Transplant Surgeons with respect to the future board of the Organ Procurement and Transplantation Network. NOTA: National Organ Transplant Act; OPTN: Organ Procurement and Transplantation Network

timelines, political influences, and exclusion of the very transplant specialists who have been involved with the OPTN in the past to provide institutional memory and transplant expertise have been essentially ignored.²⁵ Time will tell if the very organization tasked with improving the most successful transplant process in the world ends up jeopardizing its stability and impartiality.

CONCLUSION

In 1986, UNOS began operating the OPTN under a federal contract, managing national organ donation and transplantation. The heart allocation system has evolved to better define the patients in need of cardiac transplantation based predominantly around medical urgency. The current allocation system has had the greatest improvement in both waitlist mortality and improved survival following transplantation. The next heart allocation system aims to create a more seamless balance of patient and donor matching factors via a CD model and may be implemented by 2027. With the new OPTN modernization initiative, however, it is unclear what impact and alteration it will have on CD and other aspects of transplantation. The transplant community is in uncharted waters and must remain vigilant and proactive to ensure that the safety and integrity of the allocation process remains first in class.

KEY POINTS

- Organ matching was a local phenomenon until a national allocation system was developed in 1988.
- The US allocation policy has had three modifications since 1988, each improving waitlist mortality and waitlist time for the sickest candidates without compromising post-transplant outcomes.
- The future iteration of allocation will be based on a continuous model weighing donor and recipient attributes.
- In 2023, Organ Procurement and Transplantation Network (OPTN) Modernization was initiated to revamp perceived deficits in the current allocation system.
- Current disruptions in all levels of the OPTN are still being determined as to whether they help or harm the allocation process.

COMPETING INTERESTS

Shelley Hall, MD, is a consultant/advisor for Abbott, CareDx, Natera Inc., and CVRx. Amit Alam, MD, has no competing interests to declare.

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