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Continuous Distribution for Heart Allocation: Promise, Challenges, and the Path Forward

Introduction
With thousands of people with severe and potentially lethal heart disease waiting for heart transplants, the allocation of donor hearts in the United States is a critical challenge. The Organ Procurement and Transplantation Network (OPTN) Final Rule mandates the fair distribution of hearts to those most in need, and those most likely to benefit from this gift of life - posing one of the most ethically and logistically complex challenges in medicine. The United Network for Organ Sharing (UNOS), acting under contract with through the Health Resources and Services Administration (HRSA) to operate the OPTN allocation system, is responsible for maintaining policies that determine how scarce donor hearts are distributed to those in greatest need and with greatest potential for benefit (maximizing beneficence). Since 2018, the organization has embarked on a transformative project known as Continuous Distribution (CD), designed to replace rigid, categorical ("status-based") allocation rules with a more transparent, equitable, and adaptable scoring framework that can be applied across all organs.

As of summer of 2025, the CD of Hearts project has been paused. Here I hope to provide some insights about what CD is, what it promises, and how we will likely still accomplish this task. While the effort has been temporarily disrupted, CD still represents the future of organ allocation, an advancement that is not only expected but urgently needed.

How is CD different from the current system?
Current heart allocation principally takes into consideration (1) a patient's medical urgency ("Status" – 1 through 6 for adult recipients; and 1A, 1B or 2 for pediatric recipients), (2) distance from the donor (250, 500 and 1000 mile radius categorical circles) and (3) waiting time which serves as a tie-breaker for all in-category ties. There are also some adjustments for disadvantaged blood groups.Continuous distribution, in contrast, allocates based on a Composite Allocation Score (CAS), a value which is unique for every patient-donor pair. The CAS is a calculated value that includes points for urgency (in place of former "statuses"), access priorities (pediatric patients, previous living donors, waiting time), efficiency (travel distance), and biological disadvantages (sensitization or blood group disadvantages). In contrast to the current status based system, this system has flexibility in that weights of each of these elements of the CAS can be individually adjusted, new components can be added when needed, and formulas can be changed over time without disrupting the entire system. Match runs (allocation priority lists) for each new donor organ are organized from highest CAS to lowest.

The Problems Continuous Distribution Aims to Solve

-Improving assessment of urgency
The current status systems for pediatrics (1A, 1B, and 2) and for adults (statuses 1-6) are a coarse categorization of urgency, in which medical and circulatory support criteria serve as surrogate markers of illness and waitlist mortality risk. In both the current allocation system and the first version of the proposed CD system, patients who require the most invasive and urgent support measures are prioritized highest. Unfortunately, the prioritization of patients based on support modality has perverse effects on medical decision making. For years, UNOS has attempted to make adjustments to the status system to appropriately place the most urgent patients at the top statuses, but each adjustment has yielded its own challenges.

In CD, the hope is that we can transition to a system that is more granular and flexible. By creating a continuous scale, the system can be modified in small increments over time to suit the waitlist mortality characteristics of a given population. In the first planned version of CD, subgroups of patients from the current statuses will be assigned certain numbers of points, in effect creating a system of many statuses rather than the small number that currently exist.

In addition, pediatric and adult urgency will be effectively merged, creating some common urgency levels while leaving others discrete. For example, ECMO patients will share the highest level of urgency whether pediatric or adult patient age, while some groups like VAD patients will still be separated in urgency based on known risk associated with small body size, with small VAD patients having higher urgency compared with near-adult sized patients.

CD points will be designed to provide substantial score benefit to those at highest risk of death on the waitlist. In 2018, when the adult allocation system introduced the 6-status system, the greatest win of that transition was the introduction of status 1 for ECMO and nondischargeable surgical BiVAD recipients. This status was effective at prioritizing these patients sufficiently that they had significantly improved waitlist mortality under the new system. This is an important feature which has been considered when building the scale for CD medical urgency points.

-Geographic Inequity
Historically, for heart transplant, geography is relevant because travel distance impacts ischemic time, and longer ischemic time impacts the risk of primary graft dysfunction (PGD). In the late 2010's, UNOS eliminated the use of arbitrary Donor Service Areas which had led to ethical concerns and lawsuits challenging compliance with the Final Rule requirement that organ allocation be based primarily on medical urgency and best use, not arbitrary geography. But even without DSAs, current allocation depends heavily on concentric rings of distance around a donor, with priority often given to recipients geographically closer to the donor hospital. The allocation by urgency and by distance are interweaved in a complex allocation table which is not easily understood, and which can be seen as unfair when a potential recipient falls just outside of an allocation ring and falls several categories down the allocation table as a result.

CD has the potential to improve on these inequities by prioritizing nearby transplants in a gradual, consistent fashion to the degree that experts feel best serves current technology and logistics. For example, points can be awarded based on actual distances, and the point awards will not have arbitrary cutoffs of 250- or 500-mile radius. Further, a CD system that seems fair in 2027 may be easily adjusted in 2030 if technology (and economics) for organ preservation and logistics have improved to the degree that greater sharing of organs across the country is desirable, and such an adjustment will not require a complete re-tooling of the allocation system.

-Balancing Urgency and Outcomes
In heart transplantation, patients vary in their preoperative condition, and this influences their outcomes. The current system relies on transplant centers to recognize when their patient is too sick to recover from a transplant, to not provide futile transplants, guarded by the risks to their own outcomes data.

As we move towards better estimation of waitlist mortality, we will also need to be cognizant that the most acutely ill patients on the list are also at higher risk of transplant failure. Thus, outcome estimation will become an important component of CD in future versions. CD provides a system by which urgency can be balanced with other priorities (biological disadvantages, access issues, efficiency), and allows for the creation of a point category for outcome estimation or post-transplant survival. At issue with creating a survival score is that the very items which increase pre-transplant urgency overlap with the items that can decrease post-transplant survival – such as cardiovascular shock at the time of transplant, congenital heart disease, hepatic or renal impairment, presensitization, etc.
A future is foreseen when support-based urgency system will be replaced with a score more like the pulmonary lung allocation score (LAS) or the hepatic model for end-stage liver disease (MELD) score – based on lab and vital sign indicators of acute mortality risk without transplant. In fact, such a scoring system is already being developed and tested with UNOS waitlist models, potentially ready for deployment when CD undergoes it first major update.

-Transparency and Flexibility
“Tiered” frameworks like the current allocation framework are criticized as opaque, due to the complex interactions of urgency, distance, and waiting time on the allocation tables. Current allocation policy is extremely difficult to change. Tables with over 100 criteria levels are needed to dictate the order of allocation using status, distance, blood group match, and waiting time. That said, CD will not make it easy to understand a particular match run, as the formulas actually make this more complex than ever. However, the formulas and criteria will be uniformly applied and objective.

CD will help enable more flexible policy and incremental recalibration can become the mode of change rather than wholesale redesign of the system. Further, as we gather more data about post-transplant outcomes, the possibility exists to implement a predicted outcome score to add to the policy, again without need for redesigning the rest of the system.

Where are we with CD?
Each organ system is developing its CD formulas independently on a shared framework. The rollouts of each organ's system are in a pipeline - from concept, to attribute choice, to formula design, to weighting and modeling, and finally to final design and programming. The Heart CD system is now designed in fair detail and is awaiting formal modeling of several potential formulas. Public comment has been sought at several steps along the way, and will again be requested before the final CD framework is finalized. When we resume work on the CD project, we are likely about 2 years from implementation.

AOOS and its importance to Heart Allocation:
In 2025, HRSA, the federal agency overseeing UNOS, prioritized solving the current issues leading to allocation out of sequence (AOOS), and directed the OPTN to pause all new CD policy development until the issue of AOOS is addressed. AOOS is felt to be a critical issue because it represents a failure of the OPTN to meet its core responsibility of distributing organs fairly. Although the AOOS problem predominantly affects kidney allocation, the importance of this priority has derailed heart CD development, in that UNOS paused all remaining CD activity starting Summer 2025. Concurrently, OPTN also has implemented directives to develop policies regarding donation after circulatory death (DCD) and normothermic regional perfusion (NRP), which does impact heart allocation and donation. These priorities are seen as major barriers to fairness in the allocation system and have eroded the public trust in organ allocation.

AOOS refers to situations in which an organ is offered to someone other than the next-ranked candidate on a database generated match run. Over time, more and more organs are being placed out of sequence. HRSA feels that AOOS undermines public trust in the allocation system and must be urgently resolved.

The OPTN Heart Transplantation Committee has expressed to OPTN leadership strong concern about the CD pause, especially because AOOS is seen as a largely organ-specific issue in kidney transplantation. The committee warned that suspending CD development risks losing the committee's acquired knowledge, prolonging inequities, and undermining urgent progress for heart patients. The Heart Committee also designed previous projects to dovetail into CD seamlessly. For example, the policy currently approved to increase status for patients based on long VAD waiting times was designed to translate into a VAD waiting time component in the CD framework for 2027 implementation.

Looking Ahead
HRSA currently believes that the pause in CD will be a months-long, not years-long interruption.

Through 2025 and into 2026, OPTN committees are expected to focus on implementing AOOS fixes, building compliance tools, and launching the public reporting dashboard. Kidneys, as the organ type most affected numerically by AOOS, will be the first to test these new tools before they are extended to other organs.

Conclusion
Continuous Distribution represents the most significant transformation in organ allocation policy in decades. For heart transplantation, it promises to solve long-standing problems of geographic inequity, difficulty balancing urgency and benefit, and lack of transparency. The framework's composite scoring approach aligns with the ethical principles of the Final Rule and provides flexibility to evolve over time.

The 2025 pause in development, driven by HRSA's focus on Allocation Out-of-Sequence, has created frustration within the heart transplant community. Yet this pause does not signal abandonment. Instead, it reflects a recalibration: before implementing a new allocation system, the foundation of fairness and compliance must be reinforced. Once AOOS reforms are in place—likely within the next one to two years—Continuous Distribution for hearts is expected to resume.

For the thousands of patients waiting for donor hearts, the transition cannot come soon enough. By marrying urgency, benefit, equity, and transparency in a unified framework, Continuous Distribution promises a more just and effective allocation system. Its eventual adoption will mark a milestone not only in heart transplantation but in the broader story of how society chooses to steward one of its most precious and scarce resources.

