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Longer Term Follow-up on Acuity Circle Allocation Strategies in Liver Transplantation

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Abstract

Purpose of Review This review summarizes longer term follow-up of acuity circle–based distribution for livers, which was implemented on February 4, 2020.

Recent Findings After 2 years of policy implementation, the likelihood of transplant increased, while removals for death or being too sick decreased. The median transplant score was unchanged, and the variance in the median MELD at transplant decreased for OPTN regions, DSA, and state. Concurrently, median distance from donor to transplant hospital and cold ischemia times increased. A slight increase in liver non-use rate and decrease in liver utilization rate has been observed.

Summary Acuity circle–based distribution improved access to liver transplantation for the sickest patients through broader sharing, at the cost of increased travel and logistics. The continuous distribution framework may be an opportunity for the liver transplant community to further address geographic disparities in access to transplant in the United States.

Keywords Acuity circles · Liver allocation policy · Organ distribution · Waitlist mortality

Introduction

Acuity Circles: Background and Impetus for Change

In 2020, the Organ Procurement and Transplant Network (OPTN)/United Network for Organ Sharing (UNOS) implemented an acuity circle policy for the distribution of deceased donor livers. Previously, the geographic unit of allocation had been based on Donation Service Area (DSA), where organs were offered first within the DSA, then to the region, and then nationally depending on the level of acuity. Across the 11 OPTN regions in the United States, there are 57 variably sized and populated DSAs each represented by organ procurement organizations (OPOs), which are charged with the distribution of donor organs originating within the DSA.

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Geographic disparities in access to liver transplant under the DSA-based system emerged, most notably through observed variation of the median MELD at transplant (MMaT) among DSAs and liver transplant centers. Among DSAs, there was a 10.4 point range in MMaT, a 3.3-fold variation of DSA death rate, and 20.1-fold variation in DSA transplant rate [1]. As a result, candidates could (and would) travel outside their home regions or places of residence to be listed and transplanted more expeditiously, and those who did improved their probability of transplant and decreased their risk of waitlist mortality [2]. In addition, DSAs with higher MMaT had increased death rates and were more likely to contain large cities and have a higher proportion of Black and Asian patients on the waiting list [1]. These concerns regarding geographic equity in access to liver transplant were the impetus to change the organ allocation system.

The Final Rule, as outlined by the National Organ Transplant Act (2000), lays out guidance for the equitable allocation of deceased donor organs among potential recipients, and explicitly states that these allocation policies "shall not be based on the candidate's place of residence or place of listing" [3]. This statement is conditional on other necessary considerations also outlined in the Final Rule, including sound medical criteria, avoidance of non-use of organs or futile transplants, and the efficient management of organ placement.

Proposed Solutions

To address the geographic inequity, several potential solutions were considered. An initial approved proposal involved distribution by DSA with added proximity points within a 150-nautical mile (NM) circle around the donor hospital; however, in 2018, the Health Resources and Services Administration determined that DSAs were not compliant with the Final Rule and recommended that they be removed from organ allocation policy. In this context, the acuity circles model was developed, alongside a broader 2-circle (B2C) distribution model.

Acuity circles utilize concentric circles, based on MELD score and distance from donor hospital, to allocate donor livers—with the aim to reduce variation in MMaT among geographic regions. Acuity circles encompass a broader geographic area than most DSAs, without arbitrary boundary lines, allowing patients with highest need to receive priority for transplant over a larger area [3]. In brief, first any status 1A and 1B recipients within 500 NM from the donor hospital are offered the liver. If there are none or the offer is not accepted, the organ is then offered to candidates with MELD > 37 within 150 NM from the donor hospital, then to candidates within 250 NM from the donor hospital, and subsequently within 500 NM from the donor hospital. This process is repeated among potential transplant recipients by decreasing MELD score thresholds (MELD 33–36, MELD 29–32, then MELD 15–28) until the offer is accepted (Table 1).

Recognizing that some donor types are sensitive to potentially longer travel and cold ischemia times, livers from donors older than 70 years or from donors after circulatory death (DCD) are prioritized for candidates with MELD ≥ 15 within 150 NM of the donor hospital after exhausting status 1A and 1B candidates and before being offered more broadly. Exceptions are also made for donors from geographically isolated areas outside the continental U.S.; e.g. blood type O livers recovered in Hawaii and Puerto Rico are offered for all local candidates, regardless of blood type, before any candidates outside those areas. Pediatric priority also increased with this policy change, with pediatric donors being offered nationally for pediatric liver candidates before adults.

The Scientific Registry of Transplant Recipients (SRTR) modeling predicted that acuity circles would reduce mortality by prioritizing livers for the most urgent patients and reduce differences in transplant access in DSAs and regions [4]. In simulation, the variance in DSA-level MMaT decreased; transplant rates for MELD/PELD ≥ 32 increased; overall MMaT increased from 29 to 31; waitlist mortality rates and counts decreased, and there was no change in post-transplant mortality. Greater transport distances and times were anticipated, with increase in air travel. Compared to B2C models with similarly sized circles, but only one MELD/PELD threshold of 32 or 35 (thus higher priority for proximity), or circles of 150 NM, 300 NM, and 600 NM, the acuity circle model best fulfilled requirements of the OPTN Final Rule, balancing geographic constraints while prioritizing the most urgent candidates, and was approved by the OPTN Board of Directors in December 2018.

Challenges to Policy Implementation

Although the geographic disparity in organ access was well-recognized, opinions on how to address it were mixed and contentious. The acuity circle policy was implemented briefly in May 2019, but reverted in a matter of days due to ongoing legal action. Ultimately, the federal court ruled to allow implementation of the acuity circle policy to proceed, and the policy was re-implemented on February 4, 2020, replacing DSAs and regions with concentric circles for the distribution of donor livers.

Evaluating the Impact of the Policy Change

Early results of the acuity circle policy were reported, but highly confounded by the duration of follow-up coinciding with the early days of the COVID pandemic, which was declared in the U.S. in March 2020. The uncertainty surrounding the impact of COVID infection on transplant outcomes resulted in transplant centers temporarily modifying their behaviors, including pausing of waitlisting and transplant activity, making it challenging to isolate the impact of acuity circle implementation from the impact of the COVID pandemic.

In addition, the assignment of exception points in the U.S. transitioned from regional review board to a national liver review board (NLRB) in May 2019, potentially serving as another confounder when analyzing outcomes of the acuity circles policy. The NLRB standardized the types of exceptions granted in the U.S. and lowered their waitlist priority to a fixed exception score based on MMaT, impacting up to 20% of the liver transplant waiting list [5••]. In the ensuing years, the geographic unit to calculate MMaT was readjusted to align with distribution policy—DSA-based distribution (5/2019 to 2/2020), acuity circle model with a 250 NM radius around the transplant center (2/2020 to 6/2022), and acuity circle model with a 250 NM radius around the donor hospital (6/2022 to present).

Nonetheless, it was clear that the acuity circle policy change had the intended effect of broader sharing to the most acutely ill patients, with increased organ offer and transplant rates, particularly for candidates with MELD/

Table 1 Current sequence run for adult deceased donor (DBD) livers aged 18–70 years in the United States under acuity circle–based distribution (top 46). Adapted from UNOS policy 9.8.E. H, Hawaii; PR, Puerto Rico

Sequence	MELD	Distance from donor hospital	Donor ABO	Candidate ABO
1	Status 1A	500 NM	Any	Any
2	Status 1B	500 NM	Any	Any
3	Status 1A	2400 NM (H) or 1100 NM (PR)	Any	Any
4	Status 1B	2400 NM (H) or 1100 NM (PR)	Any	Any
5	37	150 NM	O	O or B
6	37	150 NM	Non-O	Any
7	37	250 NM	O	O or B
8	37	250 NM	Non-O	Any
9	37	500 NM	O	O or B
10	37	500 NM	Non-O	Any
11	37	2400 NM (H) or 1100 NM (PR)	O	O or B
12	37	2400 NM (H) or 1100 NM (PR)	Non-O	Any
13	33	150 NM	O	O or B
14	33	150 NM	Non-O	Any
15	33	250 NM	O	O or B
16	33	250 NM	Non-O	Any
17	33	500 NM	O	O or B
18	33	500 NM	Non-O	Any
19	30	150 NM	O	O or B
20	29	150 NM	O	O
21	29	150 NM	Non-O	Any
22	30	250 NM	O	O or B
23	29	250 NM	O	O
24	29	250 NM	Non-O	Any
25	30	500 NM	O	O or B
26	29	500 NM	O	O
27	29	500 NM	Non-O	Any
28	15	150 NM	O	O
29	15	150 NM	Non-O	Any
30	15	250 NM	O	O
31	15	250 NM	Non-O	Any
32	15	500 NM	O	O
33	15	500 NM	Non-O	Any
34	Status 1A/1B	National	Any	Any
35	Status 1A/1B	National	Any	Any
36	30	National	O	O or B
37	15	National	O	O
38	15	National	Non-O	Any

PELD $\geq$ 29. This led to increased travel time and cold ischemia time, as predicted. An early 6-month report suggested no change in the DSA-level variance in MMaT (12.1 vs. 12.1) and still a wide range of MMaT, from 18 to 33 [6]. In longer term follow-up at 1 and 2 years, the overall DSA-level variance had decreased, from 14.7 pre-policy to 11.5 post-policy, as did the state and region-level variance, although these differences were not statistically significant, and there remained a wide range in MMaT (18 to 34). Overall, the national median transplant score was unchanged at 28 for adult transplant recipients and decreased from 35 to 30 for pediatric transplant recipients. Table 2 summarizes the observed changes from the 2-year OPTN monitoring reports, which analyze the changes in transplant activity and outcomes in the 2-year period before and after the policy change [5••, 7, 8].

All MELD/PELD categories experienced higher liver graft offer rates post-policy. As projected, transplant rates per 100 active person-years increased for candidates with MELD/PELD $\geq$ 29. There were 207 fewer adult removals for death or being too sick, in the context of a net increase of 461 adult waiting list registrations. Pediatric waitlist

Table 2 Summary statistics from the OPTN monitoring reports: 2-year outcomes before and after implementation of acuity circles. MmaT, median MELD at transplant

	Pre-policy	Post-policy	Net
Adult			
Waitlist additions	25,140	25,601	+ 461
Removal for death or too sick	4180	3973	
Deceased donor liver-alone transplants	13,773	14,489	+ 716
Variance in MmaT			
DSA	14.7	11.5	Decreased*
State	14.8	8.9	Decreased*
Region	6.2	5.4	Decreased*
Overall MmaT	28	28	No change
Median cold ischemia time	5.60 h	5.77 h	+ 10 min
Median transplant distance from donor hospital to transplant center	72 NM	141 NM	+ 69 NM
Pediatric			
Waitlist additions	1397	1295	− 102
Removal for death or too sick	76	58	
DDLT, liver-alone	873	789	− 84
Overall median transplant score	35	30	-5
Median cold ischemia time	6.15 h	6.60 h	+ 27 min
Median transplant distance from donor hospital to transplant center	202 NM	340 NM	138 NM
National share	17.9%	60.3%	Increase
Overall			
Transplant rate (per 100 person years)			
No exception	54.4	70.6	
HCC exception	67.1	57.3	
Non-HCC exception	96.6	105.0	
Post-transplant 6-month mortality	93.5%	93.1%	No change
Deceased donors recovered	17,898	18834	
Liver discard rate	9.0%	9.5%	+ 0.5%
Donor utilization rate	72.4%	65.1%	Decrease
Median sequence number of final acceptor	5	9	+ 4
Median time from first electronic offer to cross clamp	20.1 h	22.8 h	+ 2.7 h

mortality also decreased by 18, although overall there were fewer pediatric waitlist registrations and transplants.

In a 1-year SRTR analysis after acuity circle implementation, geographic variability, as measured by the median rate ratio (MRR), representing the difference of transplant or offer rates across DSAs, did decrease, although this varied by candidate subgroups and illness acuity [9••]. Geographic variation in transplant access overall decreased after acuity circle implementation, particularly for non-exception candidates and those with MELD/PELD 29–32,but increased for candidates with hepatocellular carcinoma (HCC).

Overall, acuity circle implementation decreased the variance in MMaT, but not as pronounced as originally projected, despite the broader sharing and higher deceased donor transplant and offer rates for the highest MELD/PELD candidates. This may reflect the utility of modeling in predicting the direction of change more so than the absolute magnitude, in part related to changes in transplant center behavior that may not be reliably anticipated or modeled.

Burton et al. found that a small proportion of centers were responsible for the increase in deceased donor liver transplants (DDLTs) for patients with MELD ≥ 37 post-policy [10•]. Thirteen centers (approximately 10% of active U.S. liver transplant centers) accounted for 196 out of the 198 net increase in MELD ≥ 37 DDLTs in the post-acuity circle era. Many of these centers listed more patients with MELD ≥ 37, suggesting a change in waitlist population and practices. During this time period, there was also increased prevalence of alcohol-associated liver disease and wider acceptance of early liver transplantation for severe alcohol-associated hepatitis in the U.S. [11, 12].

A differential increase in the use of marginal donation after brain death (DBD) and DCD donors was also observed. These less-than-ideal organs were more likely to be accepted by transplant centers located in less densely populated states with lower MMaT, and used for recipients with MELD < 29 [13]. Overall, liver transplant volumes increased, despite COVID, in both historically low and high MELD regions, partly reflecting adaptations in transplant center behavior in lower MELD regions in accepting more marginal grafts [14].

The financial impact of broader sharing is also consequential—broader sharing is necessarily associated with increased travel and cost. A single-center analysis from Baylor Scott & White in Dallas before and after implementation of the acuity circles policy demonstrated 16% higher costs per accepted donor and 55% per declined donor [15•]. The authors suggested a number of reasons for these increased costs, including import fees, surgeon fees, increased acquisition fees, and flight expenses.

Beyond MMaT: Optimizing Organ Distribution

Any evaluation of temporal trends before and after policy change is subject to the epidemiologic trends of the time periods—i.e., these are observed associations and not necessarily causal. These difference-in-difference approaches do not account for concurrent trends or events, such as changing etiology of liver disease, exception point policy, or the COVID pandemic.

Transplant centers adapted in different ways to the acuity circle allocation policy and changing landscape of liver transplantation. As more time elapses, it may become more difficult to tease apart the direct impact of the policy change—and even more so since the transition to calculate MMaT around the donor hospital in June 2022, resulting in a variable MELD score for exception cases depending on the organ offer. With this change, moving forward, the field of "allocation MELD" will no longer be available for analysis. Still, it is clear that the liver transplant community has adapted and changed in ways that were not anticipated at the outset. In addition, the landscape of liver transplantation in the U.S. has also evolved due to changes in the supply of transplantable organs, the COVID pandemic, changes in listing and transplant practices for alcohol liver disease, the advent of machine perfusion techniques that are transforming the practice of liver transplantation, and transplant center financial pressures.

Although the irregular and arbitrary boundaries of DSAs were eliminated with this policy change, acuity circles introduced another geographic imbalance. The 150, 250, and 500 NM circles resulted in notable variation in size of donor pools depending on the geographic location in the U.S. For example, many coastal areas have the majority of their circles in the ocean where there are no eligible donors. Additionally, regions of the Midwest are sparsely populated, particularly compared to the very densely populated regions in the Northeast and Mid-Atlantic. Future organ distribution policy will need to address this imbalance in population density and donor supply, e.g., with variably sized circles based on the size of the eligible donor pool or total population in a circle, rather than fixed distance.

Broader sharing, while following the guidance of the Final Rule to distribute organs to the most urgent patients over as broad a geographic area as possible, is arguably less efficient, with more offers, longer travel times, and increased cost. Increased distance and travel necessarily lead to increased logistics and cost, if not cold ischemia times. Machine perfusion techniques may mitigate some of this concern by opening up opportunities for organs to travel farther. However, the downstream impact on finances (including increased costs of machine perfusion and travel) and impact of longer travel time for surgical procurement teams must also be considered. Standardized and regulated fees for organ acquisition may help to improve equity. Although the financial cost is not an explicit consideration in the OPTN directive, it does directly impact transplant center operations and their ability to provide care. The OPTN and transplant community must balance these factors as organ allocation policies are developed, and the system needs to be flexible and adapt to the needs of contemporary liver transplant candidates.

Looking Toward the Future: Continuous Distribution

The U.S. encompasses a large, diverse, and heterogeneous population, and the liver transplant system needs to work to meet their needs as equitably as feasible. In addition, there remains a finite number of organs, resulting in a supply–demand mismatch. As we have learned and observed, geographic disparity in access to liver transplantation arises from differences not only in the local organ availability, but also transplant center practices; liver disease prevalence; access to health care; the waiting list population; and the size, shape, and density of the region. Creating a uniform system is a tall task and requires a thoughtful, multipronged, and flexible approach.

The OPTN is in the process of transitioning allocation of all solid organ transplants to a continuous distribution (CD) framework with the goal of being more equitable, transparent, and adaptable. The CD framework utilizes a points-based system for organ allocation that separates the specific priorities or attributes (e.g., medical urgency, blood type, body size, or proximity) and assigns points based on variable weights [16••]. CD has already been implemented for lung allocation, and is in developmental stages for the other solid organs, with liver slated for implementation in the coming years.

Under this framework, the liver transplant distribution system may be able to better address geographic equity by balancing the various priorities of urgency, equity, and efficiency. Relative weights for each of these attributes will be determined with input from the transplant community and iteratively modeled to not only optimize waiting list and transplant outcomes, but also ensure more equitable access to liver transplantation across the U.S. The OPTN Liver & Intestine Committee has identified travel and proximity efficiency as priorities that are included as “attributes” in this framework, and is considering alternative organ distribution schemes to better address the geographic disparities in liver transplantation that still persist with acuity circles [17].

Conclusions

Variance in MMaT has been the standard by which the U.S. liver transplant community has assessed geographic variation in access to liver transplant. However, it has become clear that the geographic disparity is multifactorial and complex, and cannot be fully addressed by distribution alone, i.e., the redistribution of organs from “organ rich” to “organ poor” areas. Broader sharing helps address the mismatch in donor supply and demand, but there remain inherent differences with regard to local burdens of liver disease, OPO efficiency, and individual transplant center practices that contribute to variable organ availability, utilization, and transplantation. It may not be achievable or realistic for the MmaT to be equivalent across the country. Focusing solely on the MmaT may decrease the pressure on “organ-rich” areas to maximize the donor pool or use non-ideal donors, while penalizing centers that more aggressively pursue less-than-ideal organs to improve access to their lower MELD patients. In future policy development, outcomes beyond the variance in MmaT will also need to be considered, including transplant center organ acceptance and OPO performance.

Continuous distribution is an opportunity to address persistent deficiencies and geographic disparities in the U.S. liver transplant system, directing organs to patients in greatest need while also prioritizing proximity, efficiency, and outcomes.

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Declarations

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

Competing Interests The authors declare no competing interests.

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