Update on Organ Allocation and Liver Transplantation

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Abstract: Liver transplantation remains a lifesaving intervention for patients with end-stage liver disease; however, organ demand continues to far exceed the supply. The core ethical principles that guide scarce resource allocation include utility, equity, and prioritization of the sickest patients. Implementation of national organ allocation and distribution policy updates over the years have led to several positive changes, including earlier transplant of livers from sicker patients and decreased waitlist mortality rates. Current practices include utilization of the Model for End-Stage Liver Disease score to determine waitlist priority, with distribution protocols involving the use of the acuity circle model. Despite these improvements, geographic and socioeconomic disparities remain. This article reviews the history of liver allocation and distribution practices, the successes and challenges of current policies, and future frameworks aimed at providing equitable approaches to matching donors with candidates.

Keywords
Liver transplantation, Model for End-Stage Liver Disease score, acuity circle allocation, continuous distribution

Liver transplantation is a lifesaving treatment for patients with end-stage liver disease. According to data from the Organ Procurement and Transplantation Network (OPTN), the number of liver transplants being performed has increased, with 10,660 adult liver transplants performed in the United States in 2023, a more than 50% increase from 6730 in 2014, and the largest number to date.[1] Although waitlist numbers have slightly decreased over time, organ demand continues to far exceed the supply, and there have been revisions to allocation policies in the past several decades in an effort to promote improved and equitable distribution. This article discusses the ethical principles that have guided changes to transplant policies and how liver allocation and distribution practices have evolved and may continue to evolve.

Ethical Principles of Organ Allocation

The core ethical principles that guide scarce resource allocation include utility, equity, and prioritization of the sickest patients. First, the principle of utility in transplantation refers to maximizing the net benefit of each transplanted organ (ie, maximized patient survival rates, graft survival rates, and quality of life). The allocation of organs under the principle of utility ensures that centers strive for the best overall outcomes of the transplanted organ. Second, equity, which is based on the fundamentals of justice, strives to ensure that fair access to organ transplant is available for all patients. Equitable allocation protocols allow persons of any gender, race, or socioeconomic status to have equal access and opportunities to receive a liver transplant, embracing a concept of fair distribution. Third, prioritizing patients who are sickest ensures expedited transplant to those who are at risk of short-term waitlist mortality. It is well known that these principles can directly conflict with each other (eg, prioritizing the sickest patient may not always follow the principle of utility, as the sickest patient may still have a shorter long-term survival than others on the waitlist). There is no single ethical principle that is superior to another, and transplant centers must balance a combination of all principles to ensure appropriate organ allocation.[2,3]

Regulatory Agencies

In efforts to address the need for an organized approach and registry to match organs with individuals in the United States, the National Organ Transplant Act (NOTA) was passed by Congress in 1984. The act established the OPTN, a public-private partnership serving to manage the organ and transplant system in the United States and called for the network to be operated by a nonprofit private organization under federal contract. Since 1986, the United Network for Organ Sharing (UNOS) has held the contract with the Health Resources and Services Administration (HRSA) to operate the OPTN. In 2000, the US Department of Health and Human Services implemented the Final Rule that established the framework for the structure and operations of the OPTN. For instance, section §121.8 on the allocation of organs includes requirements that allocation policy development should be based on sound medical judgment, seek to achieve the best use of donated organs, shall be designed to avoid wasting organs and promote patient access to transplantation, be reviewed periodically and revised as appropriate, and shall not be based on the candidate's place of residence or place of listing.[4]

History of Liver Allocation and Distribution

Child-Turcotte-Pugh Scoring System

Early liver allocation systems utilized a sickest-first principle, with patients in the intensive care unit (ICU) receiving highest priority, followed by those requiring continued hospitalization, and then those at home. However, inconsistencies in ICU admission criteria arose, with some centers establishing ICUs solely for benefit of expedited access to donor organs.[5] The system also granted priority to those on the waitlist for longer times, which led to some patients being waitlisted inappropriately early solely to accrue time.[6] These issues prompted a national conference in 1996 organized by the American Society of Transplant Physicians and the American Association for the Study of Liver Diseases to formulate minimal listing criteria for liver transplantation, which proposed adoption of the Child-Turcotte-Pugh (CTP) scoring system to stratify patients based on disease severity. Although patients with imminent indications, including fulminant hepatic failure, were listed as Status 1, patients with chronic liver disease were grouped broadly into 3 categories based on CTP scores: Status 2A, Status 2B, and Status 3. However, this was an unvalidated system for organ allocation with several flaws, including the lack of a continuous score and ability to differentiate subtle degrees of disease severity as well as subjectivity of factors such as ascites and hepatic encephalopathy. Furthermore, waiting time was ultimately found to not be associated with waitlist mortality.[7,8] In response to these concerns, the Institute of Medicine advised that liver allocation should rely on objective medical criteria, with less emphasis on waiting time. Therefore in 2002, waiting time was eliminated as a major factor, and the Model for End-Stage Liver Disease (MELD) score was adopted.[9]

The Model for End-Stage Liver Disease Era

The MELD score, an objective and validated scoring system, prioritized candidates with a geographic distribution based on donation service area (DSA), where organs are offered locally first within the DSA, then to the region, and then nationally. One year following the initiation of the MELD score, reductions in waitlist mortality rates were observed, although early patient and graft survival rates remained unchanged.[10]

Over the years, there have been several critiques and refinements to the MELD score. For instance, hyponatremia was found to be a significant predictor of mortality in cirrhosis, and its incorporation into the MELD score was found to be more predictive of mortality and was associated with a decrease in waitlist deaths.[11] As a result, the OPTN updated its policy in 2016 to include serum sodium (Na) as a factor in the calculation in the updated MELD-Na score.[12] Additionally, other MELD variables, such as serum creatinine, have been shown to underestimate renal dysfunction in patients with cirrhosis for several reasons, including presence of sarcopenia (leading to decreased creatinine levels), abnormal volume status, and interference of elevated bilirubin levels with its measurement. Furthermore, serum creatinine measurements in men and women have been shown to be dissimilar, which led to women receiving up to 2.4 fewer MELD points and being listed at later stages of renal dysfunction than men with similar estimated glomerular filtration rate. Furthermore, donor and recipient matching rely on physical characteristics including height, and the likelihood of undergoing a transplant has been shown to have a linear relationship with height. Therefore, differences in physical characteristics such as height have historically disadvantaged female liver transplant recipients.[13] To address these sex-based disparities, the MELD 3.0 score was developed that uses additional variables of female sex and serum albumin, incorporating an upper limit for creatinine at 3.0 mg/dL, as well as including interactions between bilirubin and Na and between albumin and creatinine. The MELD 3.0 score was shown to have better discrimination than the MELD-Na score and reclassified nearly 9% of candidates to a higher MELD tier, with a simulation model showing fewer waitlist deaths than MELD-Na.[14] In July 2023, the OPTN updated its policy and incorporated the MELD 3.0 score, with a 3-month analysis showing that overall transplant rates significantly increased for females following implementation.[15] The MELD 3.0 score has helped overcome some sex disparities; however, other disparities such as height differences between men and women remain. A 2020 study showed that women on the liver transplant list were approximately 15 cm shorter than men, and an overall height of 166 cm (for which 72% of women were below) was associated with a significant increase in waitlist mortality.[16] Proposed solutions to overcome this disparity focus on increasing use of living donors and utilizing pediatric donors as the first offer for women, as this latter strategy was found to have a lower risk of waitlist mortality than that in women who received adult liver offers.[17]

Another critique of the MELD score is that it does not completely characterize each patient who would benefit from a liver transplant. Although higher MELD scores have been shown to be associated with short-term mortality, the MELD score has been shown to be imprecise in predicting outcomes at low scores, as these patients still experience high rates of liver-related mortality.[18] There are several conditions that are not captured by the MELD score that contribute to liver-related mortality such as hepatocellular carcinoma (HCC), portopulmonary hypertension, and hepatopulmonary syndrome, which qualify for exception points given that some of these patients have historically been disadvantaged by a low MELD score. However, the application of exception points for HCC has led to an overprioritization of patients with lower waitlist mortality and higher transplant rates. To address this, the OPTN now mandates a 6-month waiting period before exception scores are granted for liver transplant candidates with HCC. These efforts to change exception policies for HCC have led to a decrease in transplants for HCC without an impact on waitlist mortality rates.[19]

Changes in Allocation and Distribution

There have been ongoing debates about geographic disparities in access to liver transplantation (although this includes arguments about how to properly define geographic disparities). Importantly, some have argued that allocation policies involving DSAs were not aligned with the Final Rule outlined by the OPTN in 2000, which, as mentioned earlier, is that allocation policies should not rely on where a candidate resides or is registered. The following sections discuss some changes in allocation policies that have been implemented to help achieve equity and address geographic disparities. However, in the background of these changes related to geography is that there may be exceptions to the Final Rule when necessary for acceptable reasons (eg, optimizing use of donated organs or minimizing waste).[4]

Regional Share 15 Policy

After initial implementation of the MELD score in 2002, concerns were raised about geographic differences, specifically that patients with a MELD score of less than 15 in some regions were undergoing transplants earlier than patients with a MELD score of 15 or more in other regions. In 2005, in an effort to facilitate transplants of local and regional patients with a MELD score of 15 or higher, UNOS adopted the Regional Share 15 policy. The policy stated that organs must first be offered to patients with a MELD score of 15 or higher within the local DSA and then to other DSAs within the same region, before making them available to local DSA candidates with a MELD score below 15. Although this system led to a 36% decrease in candidates with a MELD score below 15 undergoing transplant, there was no change in the number of donor livers shared outside the local DSA.[20]

Regional Share 35/National Share 15 Policy

Variations in median MELD score at transplant (MMaT) have increased between DSAs, exacerbating inequities in access to transplantation. A 2012 study showed that candidates with a MELD score of greater than 35 were found to have similar waitlist mortality rates as patients with acute liver failure listed as Status 1A.[21] This prompted wider geographic sharing to improve access for candidates with high MELD scores, with simulation suggesting that regional donor organ sharing would decrease waitlist mortality rates.[22] Therefore, in 2015, the Regional Share 35/National Share 15 policy was implemented by the OPTN. Under this policy, candidates with a MELD score of 35 or higher in the region were offered the organ before local candidates with a MELD score of less than 35. Additionally, if there were no suitable candidates with a MELD score of 15 or higher, the organ was offered

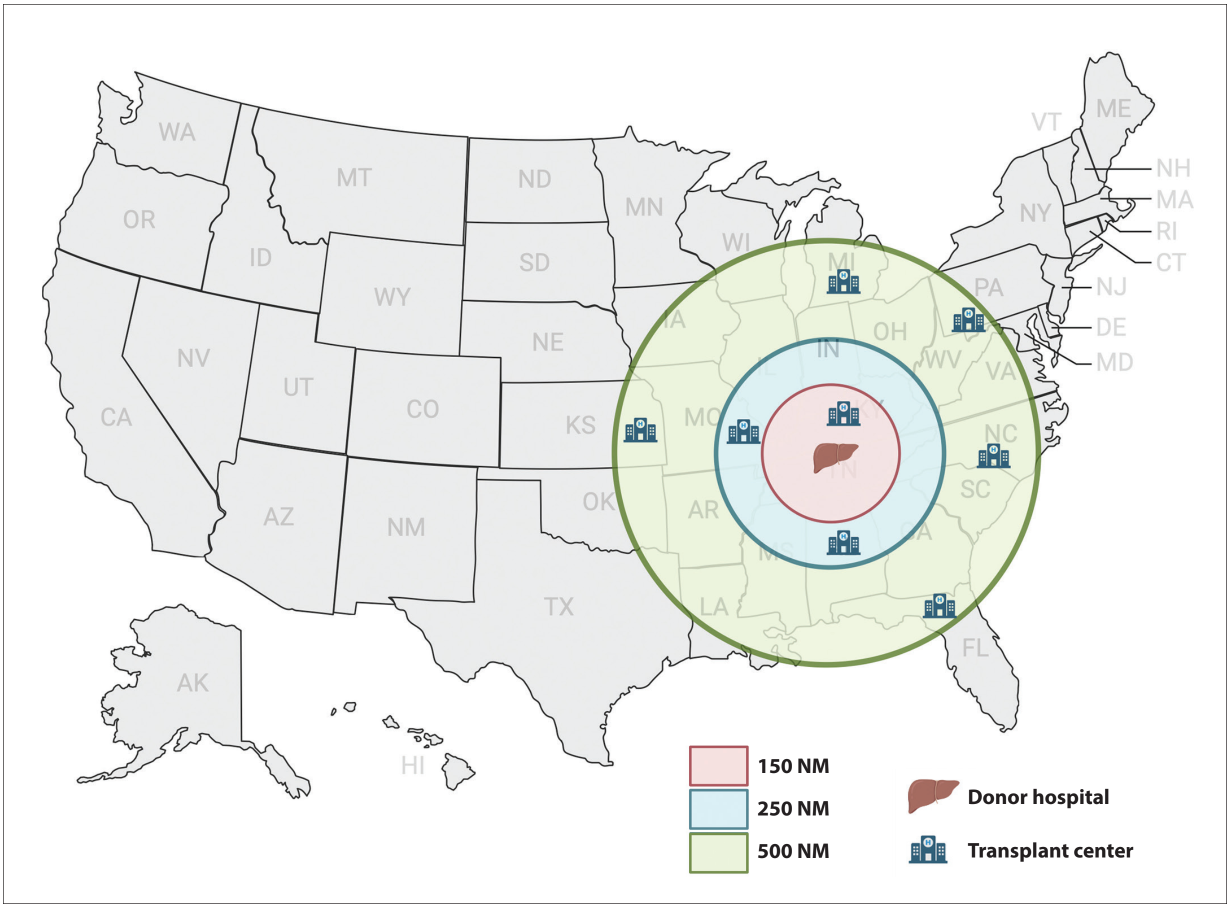

Figure. Acuity circle allocation based on distance in NM from donor hospital to transplant center for distribution of livers for transplantation. Created with BioRender.com.

NM, nautical miles.

nationally before being offered to local DSA candidates with a MELD score of less than 15. Although early studies following the Share 35 policy for liver allocation showed significant increases in the MELD score of recipients at the time of transplant, donor risk indexes were increased with no differences nationally in posttransplant survival. Furthermore, a 2016 study showed significantly worse posttransplant survival in regions 4 and 10 following Share 35.[23] Additionally, a 2017 study showed that a small subset of transplant centers were driving the increased volume of high-MELD transplants, which further supported that implementation of a national policy did not collectively lead to improved metrics at individual centers.[24]

Acuity Circle Allocation

In more recent years, geographic and socioeconomic disparities in access to liver transplantation have persisted. Significant variations have been found across DSAs, including a 3.3-fold variation in death rates, 20-fold variation in transplant rates, and a greater than 10-point mean variation in MELD scores. However, the degree of variation differed based on the metric used and the unit of geographic measurement. Furthermore, DSAs with a higher MMaT were more likely to be in larger urban areas with higher rates of listing, longer waitlists, and higher proportions of Black and Asian patients. These DSAs also were associated with more frequent dual listings at transplant centers, as some candidates would travel outside their home DSA in an effort to increase their chances of expedited transplantation.[25] In July 2018, a lawsuit was filed against the HRSA on behalf of 6 waitlisted patients in New York, Massachusetts, and California, calling for the OPTN to implement a new liver allocation policy and eliminate geographic boundaries associated with DSAs, with efforts to ameliorate the geographic variability in access to liver transplantation.[26]

In February 2020, geographic liver allocation policies were updated, and acuity circle (AC) allocation replaced the prior local allocation system based on DSAs (Figure). AC allocation utilizes concentric circles based on distance in nautical miles (NM) from the donor hospital and adheres to the following parameters to allocate organs. Any Status 1A and 1B recipients within 500 NM from the donor hospital are first offered the liver. If there are no recipients available or the liver is declined, then it is offered to candidates with a MELD score of 37 or higher within 150 NM from the donor hospital, then to candidates within 250 NM, and then to candidates within 500 NM from the donor hospital. If there are no candidates or the liver is declined, this is repeated for candidates with decreasing MELD score thresholds (MELD scores of 33-36, 29-32, 15-28, and <15) until the liver is accepted. To avoid complications associated with longer ischemia and travel times for donation after circulatory death (DCD) donors of advanced age (older than 70 years), livers from these donors are offered first to Status 1 candidates within 500 NM, and then to all candidates with a MELD score of 15 or greater within 150 NM before being offered more broadly. Notably, there is also a variance for blood type O deceased donors from geographically isolated areas outside the continental United States, such as Puerto Rico and Hawaii, whereby recovered livers are offered to all local candidates regardless of blood type, before candidates outside the area.[27] Simulated allocation models from the Scientific Registry of Transplant Recipients (SRTR) predicated that utilizing the AC model would decrease donor-specific antibody variability in MMaT, increase transplant rates for candidates with a MELD score of 32 or higher, and decrease waitlist mortality rates without changing posttransplant mortality. Transport metrics, including greater transport distances and times as well as higher air transport rates, were anticipated.[28]

In the 4 years following the implementation of the AC model, several studies examined the impact of this framework. Early results were potentially confounded by the COVID-19 pandemic, which directly impacted transplant rates and behaviors across centers throughout the United States. Furthermore, in 2019, regional review boards were replaced by the National Liver Review Board, which standardized criteria for conditions qualifying for exceptions, further affecting transplant behaviors across the country. In an early 6-month analysis on the impact of organ procurement and transplant following implementation of the AC model, continued variances in the MMaT existed, although the number of procurements with a flight-consistent distance increased.[29]

A 2-year follow-up by the OPTN showed that while variances in national median transplant scores decreased by OPTN region, DSA, and state, these changes were not statistically significant (and much smaller than predicted by SRTR), and the national median transplant score for adults remained unchanged at 28. Overall, liver transplant rates have increased for Status 1A/1B candidates and for patients with MELD scores of 15 or lower and 29 and higher, although overall liver utilization rates have decreased with higher discard rates.[30] Despite overall increased access to donor livers for candidates with high MELD scores, a large center-level variation in the number and proportion of deceased-donor liver transplant remains for candidates with MELD scores 29 and higher, which highlights imbalances remaining at transplant centers despite widespread adoption of AC allocation.[31]

Furthermore, concerns regarding increased times associated with broader sharing remain. Compared with the prior local allocation system, donor livers are now offered to nearly twice as many candidates and centers, with more centers being involved in the match run prior to being accepted.[31] Distances between donor and transport hospitals, preprocurement times, and cold ischemia times have all been shown to be higher following the implementation of AC allocation, which raises concerns of potential impact on organ quality and long-term recipient outcomes.[30,33] Further long-term data are needed to determine the long-term impact of these factors.

Additionally, financial and socioeconomic consequences associated with broader sharing following the institution of AC allocation have been raised. A single-center cost analysis of 213 donors following the implementation of AC allocation showed that the mean total costs of acquisition increased 16% per accepted donor and increased 55% per declined donor owing to import fees, surgeon fees, acquisition fees, and increased flight costs.[34] Other centers have reported similar concerns in addition to unintended consequences of exacerbation of socioeconomic disparities. A 2024 study showed that transplant centers from low-income states and centers providing care for racial/ethnic minorities including Black candidates experienced significantly increased costs for imported livers, fly-outs, and dry runs despite performing a lower volume of transplants and suggested that there may be a disproportionate burden on populations already experiencing disparities.[35]

Importantly, achieving the best overall outcomes of the transplanted organ, the core ethical principle of utility, remains to be established in the post-AC era. Although the Final Rule states that centers should aim for the best use of each donated organ, the AC model has not yet provided clear advances in this regard for liver transplantation. Currently, the Centers for Medicare and Medicaid Services monitors metrics, such as 1-year survival, closely to assess the quality of care in transplant centers. Centers with lower-than-expected 1-year survival rates may be subject to review, which can influence funding and accreditation. In the OPTN's 2-year analysis, a small nonsignificant decrease in posttransplant survival from 93.5% to 93.1% was reported.[30] Although not a clinically large difference, these statistics perpetuate the idea that a transplant recipient who has achieved 1-year survival has successfully benefited from the use of the donated organ. Inevitably, transplant centers must continue to balance who will derive the best use from the donated organ vs who will survive at 1 year.

Normothermic Regional Perfusion and Machine Perfusion

Recent advances of in situ normothermic regional perfusion (NRP) and ex situ normothermic machine perfusion (NMP) will continue to impact future transplant practices, particularly with increasing rates of DCD donor utilization. In NRP, following the circulatory arrest phase and the required no-touch period, in situ normothermic oxygenated circulation is restored, providing time for inspection, evaluation of laboratory values, and preventing a rushed recovery.[36,37] An analysis of US registry data between 2020 and 2021 showed that DCD livers procured with thoracoabdominal (TA)-NRP resulted in a significantly higher utilization rate compared with livers procured without TA-NRP, 70.6% vs 39%, respectively.[38] In contrast, NMP involves ex situ graft perfusion with oxygenated blood suspended in a nutrient-rich colloid solution at normal body temperatures, allowing the graft to maintain function under physiologic conditions. It can also serve as a preservation method, replacing traditional static cold storage (SCS). Emerging data have suggested a reduced incidence of postreperfusion syndrome, early allograft dysfunction, and biliary complications with NMP compared with SCS. However, the use of NMP remains limited to specific centers because of logistical challenges, such as device portability and perfusionist availability, and overall associated costs.[39,40]

Continuous Distribution

In 2018, the OPTN board of directors approved the continuous distribution framework for organ allocation.[41] A continuous distribution model proposes to remove existing hard boundaries between classifications in the current allocation system that prevent candidates from being prioritized higher on the match run. It also aims to improve equity for waitlisted candidates, increase transparency in the allocation system, and provide more potential for flexibility for future policy changes and implementation. There is a proposal to replace the current classification and ranking system based on the MELD score with a points-based system utilizing a composite allocation score (CAS). The CAS intends to align with requirements from NOTA and the Final Rule by incorporating a weighted sum of attributes, including medical urgency, candidate biology, patient access, and placement efficiency, although these attributes are still not finalized. Medical urgency (currently Status 1A/1B, MELD score) will attempt to prioritize patients with high mortality on the waitlist by also incorporating factors such as optimized prediction of mortality. Candidate biology (currently only candidate blood type is accounted for) has been suggested to incorporate factors such as donor-recipient size matching, frailty, surgical complexity, and human leukocyte antigen sensitization to increase transplant opportunities for candidates who are harder to match. Patient access (currently candidate age, waiting time, and liver-intestine registration) will incorporate factors such as prior living donor, willingness to accept a split liver transplant, and geographic equity in an effort to promote appropriate access to transplantation for all candidates. Lastly, placement efficiency (such as travel and proximity efficiency) and resources required will be taken into consideration when matching, transporting, and transplanting the organ. Using simulation models, the continuous distribution concept was shown to reduce patient deaths, minimizing differences in disease severity scores, and provide equitable geographic distributions for transplantation.[42] Another strength of continuous distribution is the ability to incorporate data-driven changes in real time, as new attributes can be added and weighted as deemed appropriate and implemented into the system immediately, while other outdated factors can be deprioritized (eg, improvement in allocation techniques limiting cold ischemia times). Although discussions regarding continuous distribution remain in preemptive stages, the concept continues to hold promise. Artificial intelligence (AI)-based donor-recipient matching has also been proposed as a potential way to optimize transplant logistics, enhance efficiency, and decrease both rates and costs associated with early graft dysfunction and increase graft survival rates. However, several important limitations remain, and the various proposed AI models need to be validated.[43]

Conclusion

Implementation of national organ allocation and distribution policy updates have led to several positive changes, including earlier transplant for sicker patients and decreased waitlist mortality rates. However, geographic and socioeconomic disparities have emerged over the years. Future efforts should continue to not only reevaluate and refine existing policies but also explore new frameworks that advance our ability to provide the most equitable approach to matching donors with candidates.

Disclosures

The authors have no relevant conflicts of interest to disclose.

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