Balancing Efficiency and Fairness in Liver Transplant Access: Tradeoff Curves for the Assessment of Organ Distribution Policies

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Background. Current distribution policies have resulted in persistent geographic disparity in access to donated livers across the country for waitlisted candidates. Methods. Using mathematical optimization, and subsequently the Liver Simulation Allocation Model, the following organ distribution concepts were assessed: (1) current policy, (2) proposed alternative models, and (3) a novel continuous distribution model. A number of different scenarios for each policy distribution concept were generated and analyzed through efficiency-fairness tradeoff curves. Results. The continuous distribution concept allowed both for the greatest reduction in patient deaths and for the most equitable geographic distribution across comparable organ transportation burden. When applied with an Optimized Prediction of Mortality allocation scheme, continuous distribution allowed for a significant reduction in number of deaths—on the order of 500 lives saved annually (https://livervis.github.io/). Conclusions. Tradeoff curves allow for a visualized understanding on the efficiency/fairness balance, and have demonstrated that liver candidates awaiting transplant would benefit from a model employing continuous distribution as this holds the greatest advantage for mortality reduction. Development and implementation of continuous distribution models for all solid organ transplants may allow for minimization of the geographic disparity in organ distribution, and allow for efficient and fair access to a limited national resource for all candidates.

INTRODUCTION

The US organ allocation system, administered by the United Network for Organ Sharing (UNOS), has historically distributed organs based on a “local-first” approach, whereby deceased-donor organs are offered first to patients in proximity to the donor location (ie, within the donor service area [DSA]), followed by candidates beyond the DSA but within the donor’s UNOS Region, and finally to candidates residing outside of the donor’s Region. The result has been that a candidate’s access to organ transplant has varied based on their residence within a specific DSA and UNOS Region.

In an attempt to address this geographic disparity to organ access, on April 2, 1998, the “Final Rule” was issued by the Department of Health and Human Services (DHHS) stating that organ allocation should be designed and implemented so as to prioritize waitlisted candidates in order of decreasing medical urgency status, and so that a candidate’s location should not remain a major determinant in access to transplantation.1 In the case of liver transplantation, the institution of allocation based on the model for end-stage liver disease (MELD) in 2002 fulfilled the former goal; however, the latter goal has been elusive and as nearly 2 decades later it remains clear that the geographic disparity in access to liver transplantation has persisted despite the “Final Rule.”2,3

On July 13, 2018, a lawsuit was filed in the US District Court Southern District of New York. The plaintiffs—6 individuals awaiting liver transplantation—set forth to sue DHHS, the Organ Procurement and Transplantation Network (OPTN), and UNOS, for an “illegal and inequitable liver allocation policy” that had been based on a history of “local-first” distribution.4 Notably, this lawsuit came on the heels of a court-ordered change in the nationwide lung transplant distribution policy in 2017, which abandoned the use of DSAs as initial areas of
distribution in favor of prioritizing transplant centers located within 250 nautical miles of the donor’s hospital. Subsequently, DHHS directed the UNOS Liver and Intestinal Transplantation Committee in July 2018 to develop a novel liver distribution proposal that eliminated both DSA and UNOS region as a unit of organ distribution.

The disparity between organ supply and demand represents a byproduct of medical and technological advances that have made organ transplantation the standard of care for the treatment of end-stage organ failure. Notably, the geographic areas of distribution and their boundaries were developed over 3 decades ago and were never intended nor designed to be used as areas of distribution for transplanted organs. These geographic disparities, multifactorial in their origin, have been longstanding as evidenced by extensive prior investigations into alternative models of liver distribution. Indeed, the OPTN is currently assessing guiding principles for the consideration of geography within OPTN policies for all solid organ transplants. The following three frameworks are under consideration: (1) fixed geographic areas based on the distance between the organ donor hospital and the transplant candidate’s hospital; (2) mathematical optimization of boundaries; and (3) a continuous distribution that combines important clinical factors along with proximity to the donor location.

Despite concerted efforts to address geographic disparity, there has been a persistent inability to achieve consensus from all stakeholders regarding a novel liver distribution scheme. The delicate balance between efficiency and fairness is paramount in the context of this discussion and has previously been used to analyze challenges in resource allocation through the use of tradeoffs with assigned objectives. Herein, through the generation of tradeoff curves, we sought to comprehensively analyze the implications of various liver distribution proposals based on the 3 suggested OPTN frameworks, and in doing so provide a visualized demonstration of fairness and efficiency, which favors application of a continuous distribution scoring model for candidates awaiting liver transplantation.

**MATERIALS AND METHODS**

**Background**

Liver transplantation candidates are currently prioritized based on a numerical score, ranging between 6 and 40, which reflects their predicted 90-day mortality as determined by the MELD. For distribution of a donor liver, candidates have traditionally been classified as local, regional, or national, depending on their location relative to the donor hospital. Specifically, there are 58 groupings of counties into DSAs, and these DSAs are grouped into 11 OPTN Regions. Candidates are classified as local if their transplant program is in the same DSA as the donor hospital. Broadly speaking, for bands of decreasing MELD scores, organs are sequentially offered first to local candidates, followed by regional and then national candidates (with certain exceptions for severely ill patients; see Supplemental Materials and Methods; Section A, SDC, http://links.lww.com/TP/B831).

**Distribution Concepts**

The alternative distribution concepts considered were categorized into 3 broad frameworks, as proposed by the OPTN/UNOS Ad Hoc Committee on Geography: (1) fixed distance from donor hospital; (2) mathematically optimized boundaries; and (3) continuous distribution. The majority of concepts generally follow the paradigm of classifying candidates to local/regional, and then using decreasing MELD-score bands, livers are sequentially offered locally, regionally, and then nationally. However, each concept classifies candidates as local/regional following a different process, and/or also uses different MELD score bands for distribution priority. For a detailed description of each distribution concept see Supplemental Materials and Methods; Section A (SDC, http://links.lww.com/TP/B831).

**Fixed Distance From Donor Hospital**

This framework prescribes using “concentric circles” around the donor hospital to classify candidates as local/regional. The following concept within this framework was considered:

- Acuity Circles (AC): Three enlarging circles of fixed radii around the donor hospital are used to classify candidates using MELD score bands that begin narrow for candidates with increased disease severity, but subsequently become wider at lower MELD thresholds.

Parameters considered were the circles’ radii and the MELD score bands’ ranges.

**Mathematically Optimized Boundaries**

This framework maintains the usage of distribution boundaries, similar to DSAs and/or OPTN Regions, but calls for their redesign so as to optimize organ distribution. The following concept within this framework was considered:

- Optimized Districts: Similar to existing policy, wherein existing DSAs are used; however, alternative DSA groupings into a certain number of regions are used, generated through optimization. Parameters considered were the number of regions and the possible groupings of DSAs into regions.

**Continuous Distribution**

This framework seeks to eliminate any type of geographic boundaries, be it circles or regions, and instead accounts for distance between a candidate’s transplant program and the donor hospital by incorporating it directly into the allocation score. The following concept was considered:

- Continuous Score (CS): Candidates across all transplant programs were prioritized via a unified allocation score that combined their medical urgency score (MELD) and a proximity score, which decreased proportionally to the distance of their transplant program to the donor hospital. In particular, the following allocation score was used:

\[
\text{(MELD) - } \lambda \text{ (Distance between candidate and donor hospitals)},
\]

where \(\lambda\) was the proportional factor at which the score decreased per extra unit of distance. Higher values of the parameter \(\lambda\) favored proximity over medical urgency, whereas lower values of the parameter \(\lambda\) favored medical
urgency over proximity. Varying granularity levels were considered for measuring distance; at the finest granularity level, all distances were measured in increments of 1 nautical mile (nanometers), conversely increments of 50 nm were used at the least granular level. Certain exceptions were again applied for severely ill patients (Supplemental Materials and Methods; Section A, SDC, http://links.lww.com/TP/B831).

For each distribution concept, multiple policies were generated by varying the associated parameter values, for example, the parameter $\lambda$ for CS-style policies (Supplemental Materials and Methods; Sections B and E, SDC, http://links.lww.com/TP/B831). Performance evaluation was based on the latest version of Liver Simulation Allocation Model (LSAM, version 2014), a program developed by the Scientific Registry of Transplant Recipients (SRTR) that uses historical real-world data from 2007 to 2011 to simulate the allocation of livers to candidates during that period (Supplemental Materials and Methods; Section B, and Table S1, SDC, http://links.lww.com/TP/B831).

For each generated policy, 20 simulation runs for each of years 2010/2011 were used to evaluate the following metrics of interest:

- Expected deaths (waitlist deaths, deaths after removal, and posttransplant deaths)
- Expected transplant counts and percent of organs transplanted locally (in the same DSA)
- Median MELD at transplant (MMaT)
- SD of MMaT across the 58 DSAs ($\sigma_{MMaT}$)
- Discrepancies in death and transplant rates among different age, sex, disease type and racial groups
- Average and median transport distances and times of organs
- Average percent of organs flown

Among the reference policies considered herein were the current 11-Region policy, the AC-style policy with radii of 150/250/500 nm (approved in December 2018 by OPTN), and another AC-style policy with radii of 150/300/600 nm (AC 300/600). Analysis of additional reference policies and distribution concepts is presented at https://livervis.github.io.

**Alternative Allocation Methods**

All distribution concepts were considered under 3 medical urgency scores (1) MELD, (2) MELD-Na, and (3) optimized prediction of mortality (OPOM), which has demonstrated significantly more accurate 90-day mortality prediction.10

This study used data from the SRTR, which includes data on all donor, wait-listed candidates, and transplant recipients in the United States, submitted by the members of the OPTN. The Health Resources and Services Administration (HRSA), US Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors.

**RESULTS**

The results of the LSAM runs are best illustrated in tradeoff plots that follow.
Figure 1 illustrates the tradeoff between annual average deaths (y-axis) and transport distance (x-axis). Continuous scoring policies dominated all others considered and allowed for the greatest reduction of deaths across all transport distances. Table 1 compares reference policies to CS-style policies with comparable transport distance—that is, with \( \lambda \) appropriately chosen to yield similar transportation outcomes—across multiple metrics. Of note, the current 11-region OPTN policy resulted in 2510 annual deaths, with an average organ distance travel of 244.7 nm. In comparison, utilizing a continuous distribution model while maintaining comparable organ travel distance as current policy (243.4 nm), an additional 104 lives were saved every year. For the proposed AC 250/500 and AC 300/600 policies, which resulted in 2420 and 2394 deaths, respectively, continuous distribution at comparable travel distances resulted in reductions of 30 and 24 deaths, respectively.

Figure 2 illustrates the tradeoff between the SD of MMaT across DSAs (y-axis) and average transport distance (x-axis), and again demonstrates the benefits of a continuous scoring model, when compared to all other policy concepts. Table 1 illustrates the significant reduction in \( \sigma_{MMaT} \), in the order of 10%–30%, that CS-style policies achieve vis-à-vis reference policies with comparable transport distance.

Notably, outcomes under CS-style policies were almost unaffected by varying granularity for distance measurements. In particular, policies that rounded distances to the nearest multiple of 10, 20, 30, or 50 nm yielded similar outcomes to policies that used granularity of 1 nm for distance measurements (Supplemental Materials and

<table>
<thead>
<tr>
<th>Avg. transport distance, nm</th>
<th>Deaths</th>
<th>Difference</th>
<th>( \sigma_{MMaT} )</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNOS 11-district</td>
<td>244.7</td>
<td>2510</td>
<td>3.4 (3.3, 3.5)</td>
<td>29.8% (−33.1%, −26.4%)</td>
</tr>
<tr>
<td>AC (250/500)</td>
<td>243.4</td>
<td>2406</td>
<td>−104 (−140, −68)</td>
<td>2.4 (2.3, 2.5)</td>
</tr>
<tr>
<td>AC (300/600)</td>
<td>255.8</td>
<td>2389</td>
<td>−30 (−53, −7)</td>
<td>2.4 (2.3, 2.5)</td>
</tr>
<tr>
<td>Comparable CS (( \lambda = 0.022 ))</td>
<td>294.0</td>
<td>2394</td>
<td>2.7 (2.6, 2.8)</td>
<td>12.0% (−16.7%, −7.3%)</td>
</tr>
<tr>
<td>Comparable CS (( \lambda = 0.016 ))</td>
<td>288.6</td>
<td>2370</td>
<td>−24 (−58, 10)</td>
<td>2.3 (2.2, 2.4)</td>
</tr>
</tbody>
</table>

For each of the 3 reference policies, a CS-policy (ie, a value of \( \lambda \)) was chosen that yielded comparable average organ transport distance. Reduction in both annual average deaths and SD of Median MELD at Transplant \( \sigma_{MMaT} \) across 20 iterations of 2011 simulator is reported, with the one SD confidence interval in parentheses. AC, acuity circles; CS, continuous score; MELD, model for end-stage liver disease; MMaT, median MELD at transplant; \( \sigma_{MMaT} \), SD of MMaT across the 58 DSAs; UNOS, United Network for Organ Sharing.
Methods; Section D, and Figure S4, SDC, http://links.lww.com/TP/B831).

Figure 3 plots the average deaths versus average transport distance tradeoff curve across all distribution concepts when using various allocation scores—MELD versus MELD-Na (Figure 3A) and MELD versus OPOM (Figure 3B). The tradeoffs underlying all distribution concepts studied persisted and demonstrated the same advantage in

FIGURE 3. Tradeoff between annual average deaths and transport distance for different distribution concepts for 2011 simulation, comparing (a) MELD- vs MELD-Na-based allocation and (b) MELD- vs OPOM-based allocation. AC, acuity circle; CS, continuous distribution; MELD, model for end-stage liver disease; MELD-Na, sodium-enhanced MELD; OD, optimized districts; OPOM, optimized prediction of mortality.
a continuous distribution model for both MELD-Na- and OPOM-based allocation. Notably, OPOM (versus MELD) allocation resulted in substantial mortality reduction on the order of 500 lives saved annually that was uniform across all distribution concepts. Other tradeoffs concerning different metrics were also explored—for example, average deaths versus organ transport times (Supplemental Materials and Methods; Section C, and Figures S1–S3, SDC, http://links.lww.com/TP/B831). A full exploration of these concepts is available at https://livervis.github.io, where a systematic exploration can be undertaken of other tradeoffs concerning all metrics of interest.

Finally, the utilization of grafts from (1) donors >70 years old, (2) donation after circulatory death (DCD), and (3) donors with macrosteatosis >30% was analyzed, to determine the impact of transport distance on these marginal grafts. Table 2 demonstrates that increased travel distance was associated with a trend in increased discard rates and decreased average graft survival for marginal grafts.

The data reported here have been supplied by the Minneapolis Medical Research Foundation as the contractor for the SRTR. The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy of or interpretation by the SRTR or the US Government.

**DISCUSSION**

To promote access and efficiency, the Final Rule mandated that organ allocation not to be based on the transplant candidate’s place of residence or listing—except as required by sound medical judgment and best use of donated organs to avoid wasting organs and futile transplants. Yet, a geographic disparity in access to organs exists. For liver transplantation, this persistent discrepancy has manifested in differences in median MELD scores at transplant, rates of waitlist mortality, and ultimately has resulted in differential patterns of clinical practice by transplant professionals and candidates awaiting transplantation. The use of living-donor liver transplantation, a high-risk surgical endeavor, has largely been relegated to those areas of the country where the discrepancy between supply and demand is the greatest. In addition, those socioeconomically privileged candidates who can travel, choose to do so by “migrating” to areas with lower MELD scores at transplant in order to achieve liver transplant in an expedited fashion, and subsequently return with their new liver graft to their home.

The liver transplant community has remained divided over the discussions surrounding broader distribution of deceased-donor liver grafts. Indeed, the geographic disparity in access to organs remains a contentious topic that has progressed from a debate among medical professionals to now resulting in a litigious intersection with law, politics, and policy. Although in December of 2018, the UNOS Board of Directors voted to support an AC approach to liver distribution with the hopes of achieving a more consistent and equitable approach to distribution, this by no means represents a mathematically optimized approach. Indeed, in December of 2018, the UNOS Board of Directors also approved the recommendation from the UNOS Ad Hoc Geography Committee to use continuous distribution as a model for developing future organ distribution policies—a direction supported herein by the first

<table>
<thead>
<tr>
<th>Table 2: Utilization of marginal grafts for reference policies vs CS-style policies with comparable transport distance</th>
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<tr>
<td><strong>Donor age &gt;70 (N = 241)</strong></td>
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<tr>
<td>--------------------------------</td>
</tr>
<tr>
<td>UNOS 11-district</td>
</tr>
<tr>
<td>Comparable CS (250/500)</td>
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<tr>
<td>AC (250/500)</td>
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<tr>
<td>Comparable CS (300/600)</td>
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<td>AC (300/600)</td>
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demonstration of the potential application of a boundaryless CS in liver distribution.

Paramount to achieving consensus on an approach to address geographic disparity is the need for a balance between efficiency and fairness. We have previously extensively analyzed this dilemma as it relates to resource allocation through the use of tradeoffs with assigned objectives and herein applied this framework to comprehensively analyze outcomes of various liver distribution concepts. This analysis has allowed for an in-depth, mathematically optimized, data-driven analysis of tradeoffs underlying each distribution concept. Tradeoff analyses of this kind have allowed for a methodical comparison of different distribution frameworks in terms of achievable outcomes of interest. The data in Figure 1, for example, revealed how many extra lives each framework can save per additional transport mile incurred, while Figure 2 reveals how much “fairer” distribution can be by minimizing differences in disease severity scores at transplantation per extra mile.

The generated tradeoff curves have demonstrated that a continuous scoring model achieved the greatest benefits both in terms of efficiency and fairness. Indeed, for any amount of transport distance incurred, there exists a CS-style policy that achieves both the lowest number of deaths, and the lowest SD of MMaT, among all other suggested policies. Tradeoff curves have allowed for a complete assessment of all policies simultaneously to provide the framework for an informed decision—a decision that the transplant community will have to pursue in selecting the single policy that achieves their desired outcome. Although the OPTN’s Liver Intestine Committee accepted MMTa as a metric of geographic disparity in liver allocation in March of 2013, it is important to note that tradeoff curves assessing additional metrics of community interest can be generated to aid the decision making process.

Although the issues of liver distribution have remained in the forefront of discussions, it is important to note that there is significantly higher potential impact in lives saved through a more accurate and objective prioritization of candidate disease severity in liver allocation. An OPOM (http://www.opom.online) was recently developed utilizing machine learning models trained to predict any adult candidate’s 3-month waitlist mortality based on 28 variables. Indeed, OPOM allocation, when compared to MELD, reduced mortality on average by 418 deaths every year in LSAM analysis. An examination of liver distribution policies as applied through a MELD- versus OPOM-based allocation score not only reaffirmed that OPOM results in a significant number of additional lives saved every year, but also that OPOM allocation combined with a continuous scoring distribution policy maximized this potential (556 lives saved annually).

Limitations of this study include that estimating number of deaths averted using LSAM may represent an overestimation, and that LSAM cannot account for changes in practitioner listing or acceptance behavior; however, it is important to note the ability of LSAM to predict the overall directionality of change in assisting in organ policy development. In addition, the approach herein was only 1 possible implementation of continuous distribution, utilizing a simple linear function of distance with disease severity. Snyder et al eloquently delineated other continuous distribution models that entail nonlinear functions of distance. Although such more advanced models might not be as simple to communicate to patients and transplant professionals as the linear model considered here, they represent more general models that can only potentially further improve outcomes. To alleviate disparity concerns of a linear continuous distribution model on candidates awaiting liver transplant separated by small distances (ie, 2 hospitals on opposite sides of town), a continuous scoring distribution model with rounding of distances at different granularity levels was created and in simulation demonstrated the same potential improvements in transplantation outcomes independent of the distance measurement granularity.

In summary, the transplant community has now accepted the concept of continuous scoring distribution policies to allow for a more equitable and boundaryless organ distribution. We now demonstrate application of this concept utilizing the model of liver distribution. This first application of a continuous distribution score for liver transplantation demonstrates superiority to all other policies currently employed or considered, and warrants similar consideration for other forms of solid organ transplants.

REFERENCES

2. Axelrod DA, Vagefi PA, Roberts JP. The evolution of organ allocation: the transplant community will have to pursue in selecting the single policy that achieves their desired outcome. Although the OPTN’s Liver Intestine Committee accepted MMTa as a metric of geographic disparity in liver allocation in March of 2013, it is important to note that tradeoff curves assessing additional metrics of community interest can be generated to aid the decision making process.

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