REVIEW

Continuous distribution as an organ allocation framework

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Purpose of review

The Scientific Registry of Transplant Recipients (SRTR) supports the Organ Procurement and Transplantation Network (OPTN) efforts to better align liver allocation with the Final Rule. Here, we review recent literature related to removing place of residence or listing from organ allocation policy and describe how SRTR may help advance the OPTN policy development process.

Recent findings

In December 2018, the OPTN Board of Directors endorsed the recommendation from OPTN's ad hoc Committee on Geography to develop organ-allocation policies that do not rely on geographic boundaries, called 'continuous distribution.' Many objections to wider organ distribution stem from efforts to address inequities in allocation for populations within geographic regions rather than for individual patients. A continuous distribution system could equitably address the needs of individual patients, merging ethical–medical urgency with geographic feasibility.

Summary

The effort to remove geographic boundaries from organ distribution and allocation has been controversial. An integrated continuous distribution system may help focus the debate on priorities that matter most to patients.

Keywords

liver transplantation, organ allocation, organ procurement, Organ Procurement and Transplantation Network, Scientific Registry of Transplant Recipients

INTRODUCTION

The Organ Procurement and Transplantation Network (OPTN), managed by contract from the Health Resources and Services Administration (HRSA) to United Network for Organ Sharing, is charged with setting organ allocation policies in the United States [1]. The Scientific Registry of Transplant Recipients (SRTR), managed by contract from HRSA to Hennepin Healthcare Research Institute, is contracted to provide analytical support to OPTN. SRTR does this principally by fulfilling formal data requests designed to support OPTN policy development. The simulated allocation modeling (SAM) software, a set of tools developed by SRTR over the years, currently consists of three distinct pieces that model liver allocation (LSAM), thoracic allocation (TSAM), and kidney and pancreas allocation (KPSAM). Simulations necessarily make simplifying assumptions and therefore have limitations, but they can be useful in assessing the potential effects of policy changes.

The evolution of OPTN liver allocation policy has traditionally relied on categorizations of transplant candidate medical urgency and geography, namely the location of a candidate's transplant program relative to the donor's location, categorized by OPTN donation service area (DSA) and Region. Two decades ago, the notion that allocation should rely on categories was challenged:

> An underlying conceptual problem at present is the categorical rule structure. This violates the statistical happenstance in possible donor-recipient pairings that is due to the relatively small numbers of donors and simultaneously critically ill recipients. . . . greater fairness could be achieved by broader sharing . . . The principles guiding this

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KEY POINTS

- The SRTR is a valuable resource for the transplant community and for the OPTN in its efforts to examine the potential effects of changes in organ allocation and distribution policy.
- In December 2018, the OPTN Board of Directors passed a resolution mandating the development of continuous distribution allocation systems.
- SRTR is currently exploring how an organ allocation system might take into account both medical–ethical needs and geographical feasibility in a comprehensive point system.
- Although a continuous distribution system will not obviate the need for the transplant community to make difficult decisions, it may help make the process more transparent.
- SRTR is also updating the simulated allocation modeling software to better facilitate data requests from OPTN committees and improve the software for outside investigators.

> approach are: (i) no fixed geographic boundary is used throughout the United States for allocation; (ii) provision is made for the practical, medical, and financial justification for local use, in the common settings in which there is no advantage due to happenstance of a more distant use; and (iii) urgency plays a quantified and critical, but not categorical, role.... [2]

The suggestion that the liver allocation system could replace categories, especially geographic categories, with a continuous, weighted point system was never adopted. However, at its December 2018 meeting, the OPTN Board of Directors decided to eliminate geographic boundaries by adopting a continuous distribution system.

WHAT IS MEANT BY A CONTINUOUS DISTRIBUTION FRAMEWORK?

The OPTN Concept Paper 'Continuous Distribution of Lungs,' prepared by James Alcorn and released in August 2019 for public comment put forward that:

> Continuous distribution will prioritize waiting list candidates based on a combination of points awarded for factors related to medical severity, expected posttransplant outcome, the efficient management of organ placement, and equity. Continuous distribution will eliminate hard boundaries, which currently preclude a patient from being prioritized ahead of patients on the other side of the boundary. [3]

The key elements of continuous distribution allude to the Final Rule (Table 1) [1]. SRTR has described in simple terms how a continuous distribution framework could be used to replace current geographic boundaries: medical priority could be combined with geographic feasibility in a global allocation score that eliminates finite geographic boundaries (Fig. 1) [4▪▪]. All geographic boundaries create situations in which one individual a few miles on the 'wrong' side of the boundary is much less likely to receive a life-saving organ than another individual on the 'right' side of that boundary, that is, only by virtue of geography and in clear violation of the Final Rule.

Although continuous distribution has been discussed as a way to address inequities in existing organ allocation policies because of geographic

Table 1. OPTN Final Rule organ allocation requirements [1]

§ 121.8 Allocation of organs
(a) Policy development. The Board of Directors established under §121.3 shall develop, in accordance with the policy development process described in §121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:
Shall be based on sound medical judgment
Shall seek to achieve the best use of donated organs
Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4), (d), and (e)
Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate
Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement
Shall be reviewed periodically and revised as appropriate
Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program
Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)–(5) of this section

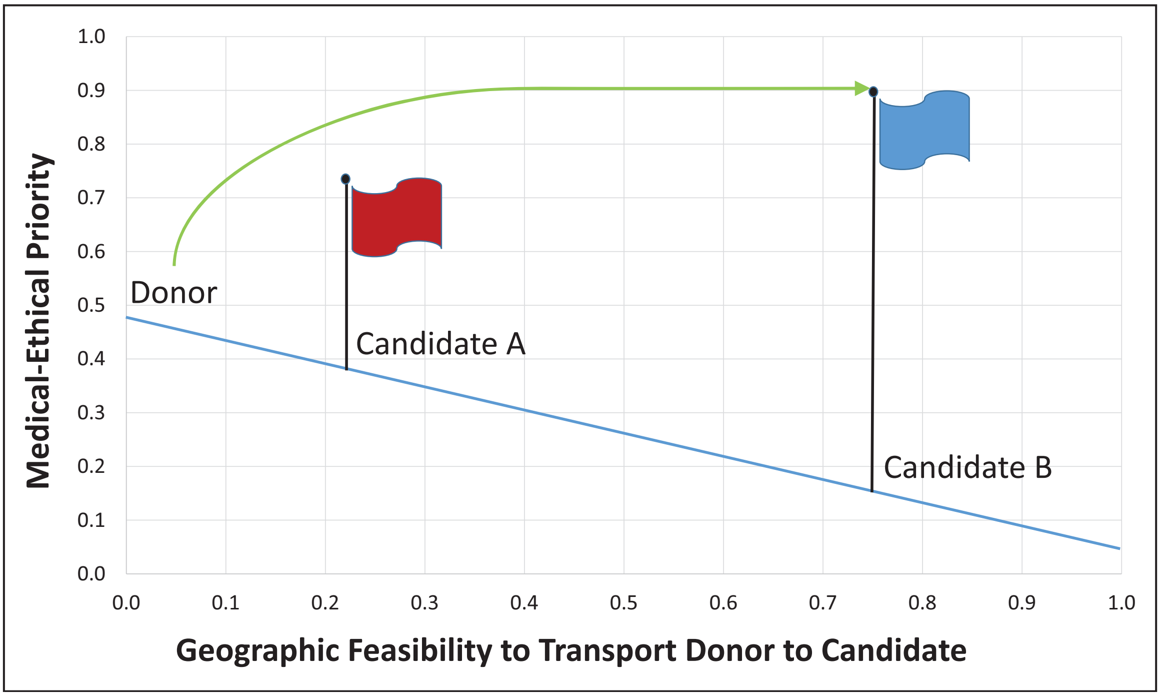

FIGURE 1. Schematic representation of how medical–ethical priority (height of the candidate flagpoles) could combine with geographic transport feasibility (downward-sloping blue line) to transport a deceased donor organ to the candidate with the highest overall priority. In the case shown, the medical–ethical priority of Candidate B exceeds that of Candidate A enough to overcome the geographic feasibility constraints of transporting the organ past Candidate A to Candidate B. Adapted from Figure 1 in Snyder *et al.* with permission [4▪▪].

boundaries, a points system will be necessary to incorporate other allocation priorities that have previously been implemented using geographic boundaries. For example, if the transplant community wishes to increase the chances of a child receiving an organ, or a previous organ donor, appropriate points must be included in a global formula to accomplish this. In existing allocation rules, children are prioritized via the local/regional/national hierarchy, so eliminating this hierarchy requires designing a pediatric priority bonus. Thus, the medical priority score might be more appropriately referred to as a *medical–ethical* score. These medical–ethical points must also address the difficult question of *how much* more likely such individuals should be to receive organs than others on the waiting list.

WHAT MIGHT A CONTINUOUS DISTRIBUTION SYSTEM LOOK LIKE FOR LIVER TRANSPLANT?

Table 2 begins to address some of the details that OPTN and others will need to confront in moving to a continuous distribution system. Geographic feasibility will need to consider the type of organ donation, for example, donation after circulatory death (DCD), the effects of organ preservation techniques, travel mode, new technologies, and other factors that may affect the organ's tolerance to ischemia resulting from travel time.

Table 2. Questions to be addressed in a continuous distribution score

Can a single 'medical-ethical' priority score combine all criteria for
Social priority (e.g., age younger than 18 years or former organ donor)[a,b]
Medical urgency[a,b]
Donor/candidate compatibility (feasibility)[c]
Candidate waiting time (fairness)?[f]
If not, can one or more criteria be used as a 'filter' that allow the rest to be combined?
Can a single 'geographic feasibility' score account for effects on
Waiting list survival[b]
Transplant survival[e]
Organ utilization[d]
Logistics and cost?[g]

Final Rule constraints that may justify using a candidate's place of residence or place of listing:
[a]Sound medical judgment.
[b]Best use of donated organs.
[c]Specificity to each organ time and candidate.
[d]Avoid wasting organs.
[e]Avoid futile transplants.
[f]Promotes patient access.
[g]Promotes efficient management of organ placement.

Any allocation system must equitably account for the use of liver transplant to treat patients with hepatocellular carcinoma (HCC). This is now addressed by assigning model for end-stage liver disease (MELD) exception points via the National Liver Review Board [5]. A recent study suggesting that liver transplant offers only a marginal survival benefit compared with other HCC treatment modalities demonstrates the need to continually address how exception points are awarded [6▪]. This may be possible to do transparently, building specific criteria for exception points into a continuous distribution score [7,8].

Recently, Bertsimas *et al.* [9▪▪] used machine learning to optimize the prediction of mortality (OPOM) for candidates on the waiting list and showed that the OPOM prediction was superior to MELD. These authors went on to examine continuous distribution point systems, determining allocation points, for example, as MELD $-\lambda\times$ (Distance between candidate and donor hospitals), where λ is a proportional factor that decreases by each unit of distance, with higher values of λ favoring proximity over medical urgency, and lower values favoring medical urgency over proximity [10▪]. Similar allocation scores could be calculated replacing MELD with an OPOM score. The authors compared different allocation schemes with LSAM and found that a continuous distribution system using OPOM produced the lowest overall mortality. However, whether the transplant community will be willing to adopt a 'black box' allocation-distribution policy remains an open question.

SHOULD ORGANS BE ALLOCATED TO INDIVIDUALS OR GROUPS?

Opponents of recent proposals for broader geographic sharing of livers have suggested that broader sharing 'siphons' donated livers from poor rural areas into wealthy urban areas, and from areas with high donation rates into areas with low donation rates [11–13]. They argue that geographic differences in socioeconomics lead to geographic inequities in access to transplant. However, allocation and distribution of organs must be to *individuals* and not to groups of individuals defined by geographic regions or demographic characteristics. OPTN does not currently collect socioeconomic data, such as household income, on individuals, but does collect some surrogate data linked to socioeconomic data, such as education and insurance status.

In 2018, a proposal was developed by the OPTN Liver Intestine Committee to replace DSA and OPTN Regions with circles [14]. The Liver Intestine Committee asked SRTR to examine the effects of this proposal on socioeconomic status. In addition to education and insurance type, SRTR examined the effects of the proposed changes in allocation and distribution on socioeconomic status using a cumulative community risk score [15] and 'urbanicity,' defined by US population census tracts as metropolitan, nonmetropolitan, micropolitan, small town, and rural, as requested. SRTR found that the proposed changes had little effect on patients described by education, insurance type, cumulative community risk score, or urbanicity [16].

Ascribing characteristics of broad geographic areas to individuals living in those areas is an ecological fallacy to be avoided. It is not appropriate to assign risks, or ease of access to organ transplant, to individuals within a community grouping based on geography or socioeconomic status because not everyone in the grouping shares those characteristics. A basic tenet of organ allocation in the United States is to allocate and distribute organs to individuals and not to groups or geographic regions or the transplant programs representing them [17]. A continuous distribution system is optimally designed to do this and to avoid organ distribution based on geographic or other boundaries and arbitrary groupings.

HOW SHOULD WE MEASURE SUCCESS?

Typically, OPTN committees make formal data requests to SRTR to examine the effects of proposed changes in allocation policy. After consulting closely with committee leadership, SRTR embarks on an analysis of the potential effects of policy changes, using historical data on waiting lists, organ acceptance decisions, and transplant outcomes. An important consideration is what metrics to use to judge whether the possible consequences of proposed allocation changes are favorable or unfavorable, intended or unintended. Typically, transplant professionals want to compare metrics reflecting current policy with metrics reflecting proposed policy changes, including deaths on the waiting list, risk of death on the waiting list reflected in medical urgency metrics such as MELD, numbers of transplants or transplant rates, numbers of organs recovered for transplant but not transplanted (also known as 'discards'), and posttransplant deaths and graft failures.

The SAMs do not and cannot identify features related to organ utilization, such as organ procurement organization (OPO) willingness to pursue nonideal donors, changes in program offer acceptance behavior, and delays in organ placement. Thus, the numbers of transplants or transplant rates in the SAMs should not be considered definitive predictions of increases or decreases in transplants, and results from the SAMs should not be compared on this metric.

The liver transplant community has often used the median allocation MELD at transplant as a measure of disparity in organ allocation. For example, geographic differences in access to transplant have been assessed using the variance in the median allocation MELD at transplant across DSAs. However, the median incident rate ratio (MIRR) of deceased donor liver transplants may be a better metric for heterogeneity across DSAs [18▪]. The MIRR takes into account time-varying allocation MELD and characterizes the variation in transplant rates per waitlist-year across DSAs. Possibly, other metrics can and should be used to assess changes in organ allocation.

The supply/demand ratio has also been used as a metric to gauge geographic disparity. Haugen *et al.* [19] defined liver supply/demand as the number of donor livers from a DSA, or from a geographic area defined by a circle, divided by the waitlist size of programs receiving livers from these donors. They found that the recently proposed 150-mile-radius circle did not reduce geographic disparity in supply/demand compared with the current DSA. Only when the circle radius was increased substantially was variance reduced.

There is no disagreement that OPO performance should be better assessed and improved [13]. For example, OPOs and transplant programs vary widely in use of DCD livers [20,21,22▪▪]. However, allocation and distribution of organs should be patient-centric, based on individuals and not on OPO performance. Patients should not be disadvantaged if the DSA in which they happen to reside is less efficient than other DSAs in retrieving organs for transplant.

Cost is difficult to account for in an organ allocation system. Although transplant program and OPO costs may increase, reduced time on the transplant waiting list may lead to an overall reduction in costs to patients and to payers such as private insurance companies or the US Government [23]. Organ acquisition costs for transplant programs can be recovered through Medicare standard acquisition fees. In addition, costs often change with market forces. If in the future more organs travel farther, the marketplace may encourage greater efficiencies using, for example, improved organ preservation techniques and other technologies [24▪,25,26]. Nevertheless, no matter what they are, costs can be built into an organ allocation model by appropriately weighting travel time along with resulting effects of cold ischemia time.

To what extent 'utility,' as measured by posttransplant survival, should be included in any allocation system is also debated. In a recent study, Bitterman and Goldberg [27] suggested that transplanting older livers into older recipients and vice versa yields better overall posttransplant survival. An accompanying editorial suggested that age matching should be considered in liver allocation [28]. A utility metric such as survival after transplant can be used in assessing continuous distribution models. Indeed, the OPTN kidney allocation system adopted in December 2014 includes an estimated posttransplant survival score in allocation prioritization (OPTN Policy 8) [29]. Similarly, the lung allocation score currently incorporates predicted pretransplant and posttransplant survival. How utility metrics are weighted is something that the transplant community and the US Department of Health and Human Services (HHS) will need to grapple with, but a continuous distribution model can facilitate the discussion by optimizing transparency.

CAN THE PAST PREDICT THE FUTURE?

Changes in behaviors must be considered when interpreting the results of statistical modeling of potential allocation changes. The recent Share 35 policy change in liver allocation affords us a good example. In 2012, Sharma *et al.* pointed out that mortality for waitlist candidates with MELD 36–40 was just as high or higher than mortality for Status 1A candidates, who received organs shared more broadly than high MELD candidates did [30]. SRTR used the LSAM to model an allocation system change whereby organs for waitlist candidates with MELD above 35 were shared regionally, rather than by DSA. The policy was ultimately adopted and implemented on June 18, 2013. This created an opportunity to test how well LSAM modeling forecasts predicted what actually occurred after implementation [31▪].

The LSAM predicted that the Share 35 policy would, as intended, increase transplant rates for candidates with MELD/pediatric end-stage liver disease (PELD) 35 or higher, and decrease rates for those with MELD/PELD under 35. This was what was observed, although the absolute numbers in the LSAM modeling results differed from those observed (Tables 3 and 4). LSAM modeling necessarily omits multiple listing, multiorgan allocation, the logistics of placing organs, and changes in organ acceptance that might result from allocation changes; thus, it reliably predicts only the direction of change, not absolute numbers of events.

LSAM modeling is done using actual data from prior transplants under the policies existing at the time. As a result, LSAM cannot be expected to predict changes in behaviors, for example, who programs list and what organs they accept for transplant, which may result from transplant programs adapting to the policy change.

Table 3. Predicted and observed transplant rates by waitlist urgency status

Waiting list urgency priority	LSAM Pre-Share 35	LSAM Share 35	Observed Pre-Share 35	Observed Share 35
Status 1A	5639	↑5916	4961	↑5218
Status 1B	529	↓518	982	↓695
MELD/PELD ≥ 35	862	↑1258	1086	↑1478
MELD/PELD 30–34	397	↓393	464	↓313
MELD/PELD 25–29	136	↓134	146	↓137
MELD/PELD 15–24	29	↓29	44	↓38
MELD/PELD < 15	0.3	↓0.1	1.8	↓1.6

Values are transplant per 100 years on the waiting list. Data are from Table 3, Goel *et al.* [31▪].
LSAM, Liver simulated allocations model; MELD, model for end-stage liver disease; PELD, pediatric end-stage liver disease.

Table 4. Predicted and observed death rates by waitlist urgency status

Waiting list urgency priority	LSAM Pre-Share 35	LSAM Share 35	Observed Pre-Share 35	Observed Share 35
Status 1A	458	↑502	542	↓396
Status 1B	47	↓45	45	↓44
MELD/PELD ≥ 35	105	↓100	157	↓143
MELD/PELD 30–34	29	–29	16	↑18
MELD/PELD 25–29	8	↓8.0	6.4	↑7.1
MELD/PELD 15–24	3.4	–3.3	5.5	–6.1
MELD/PELD < 15	0.5	↓0.5	2.6	↓2.6

Values are deaths per 100 years on the waiting list. Data are from Table 4, Goel *et al.* [31▪].
LSAM, Liver simulated allocations model; MELD, model for end-stage liver disease; PELD, pediatric end-stage liver disease.

Share 35 was designed to allocate relatively more deceased donor livers to candidates on the waiting list with MELD/PELD 35 or higher, not to reduce geographic disparities by redistributing livers. Thus, it should not be surprising that a recent study by Bowring *et al.* [18▪] found that Share 35 had little effect on geographic disparities, which remained a major source of heterogeneous access to liver transplant. Similar results were reported by others [32].

HOW CAN OTHER INVESTIGATORS EXPLORE NOVEL ALLOCATION AND DISTRIBUTION STRATEGIES?

Some investigators have used SRTR LSAM software to develop and test alternative allocation systems that address geographic disparities [9▪▪]. However, others examining alternative methods of liver allocation have found it difficult to work with SRTR LSAM models, as the software has undergone frequent revisions and updating. Kilambi *et al.* [33] developed their own modeling software, and ultimately proposed a 'concentric neighborhood' solution to the problem of geographic disparities [34]. SRTR is currently rebuilding the SAM software and working with HHS to make the software open-source and more accessible to investigators.

CONCLUSION

Recent attempts to better align organ allocation with the mandates and goals of the Final Rule have been understandably controversial. SRTR is prepared to assist OPTN in developing policies that meet the OPTN Board of Directors' mandate using a transparent continuous distribution system. In addition, SRTR is in the midst of updating the LSAM software and working with HHS to make it open source and more readily available for outside investigators.

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Conflicts of interest

There are no conflicts of interest.

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