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Liver Allograft Allocation and Distribution: Toward a More Equitable System

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Abstract The liver allocation system in the USA has undergone an evolution during the last 25 years from one largely based on waiting time to one based on disease severity. Utilizing the Model for End-stage Liver Disease (MELD) score resulted in objectively ordering the waitlisted candidates in a "sickest first" manner. However, the geographic boundaries that define the 58 donor service areas, which define the area of distribution of organ donors, as well as the MELD exception policies (particularly related to hepatocellular carcinoma) have created inequity in the organ allocation system such that patients that reside in a certain geographic location, or patients with certain diagnoses, experience differential access to liver allografts. Addressing and improving these inequities involve complex and controversial actions and thus remain a difficult charge. The following discussion includes the history of liver allocation, the changes in policies that have been recently implemented, and where distribution policies may be headed in the future.

Keywords Liver allograft allocation · Distribution · Liver transplantation · Inequities

Introduction

Liver transplantation has evolved during the past 50 years from an experimental curiosity to the definitive treatment of choice for end-stage liver disease, cirrhosis, liver cancer, and some metabolic diseases. In many ways, the field has become a victim of its success, as increasing demand has outstripped the supply of organs, necessitating the use of suboptimal grafts, expansion of the donor pool, and technical advances, such as split liver transplantation, and living donor liver transplants. As patients, physicians, surgeons, and transplant centers vie for a limited supply of deceased donor organs, there has been controversy surrounding the distribution and allocation system by which deceased donor liver allografts are matched with recipients. Most recently, the inequities caused by the current allocation system and how to address them have been hotly debated. The current organ allocation system seeks to distribute organs in a fair, efficient, and utilitarian fashion, but these principles can at times conflict with each other, and their definition, as well at what metrics to use to measure them are critical in the discourse.

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History

As human liver transplantation evolved from a futile exercise in experimental procedures, to an acceptable mode of treatment, to the treatment of choice for end-stage liver disease, the demand for organs rose exponentially. As late as in 1983, there were only four medical centers performing liver transplants in the USA, but liver transplantation quickly blossomed as the revolution in immunosuppression and control of infections improved outcomes to the point where it became clear that liver transplant was no longer an experimental treatment. Demand increased exponentially, and as a result, we presently have 143 liver transplant programs in the USA according to the latest report from the Scientific Registry of Transplant Recipients (SRTR) [1]. In 2014, there were 6449 deceased donor liver transplants performed in the USA. During the same period, 1530 candidates were removed from the waitlist due to death; while there are still 15,000 patients waiting for a liver transplant [2]. In addition, true demand may be significantly larger in magnitude as there is no accurate account of the number of patients referred to a transplant center but deemed not to be an appropriate candidate for liver transplantation.

In 1984, the National Organ Transplant Act (NOTA) was enacted and mandated the establishment of the Organ Procurement and Transplantation Network (OPTN). A key tenet of NOTA was the principle that each deceased donor organ would be considered a national resource that should be used for the public good [3]. Since this time, organ allocation policy and its development and implementation have been accompanied by vigorous debate and controversy. Every single change in organ distribution has been discussed, often in politically charged fashion, and has been framed in definitions of utility, efficiency, and equity. In June 1994, the United Network for Organ Sharing Board of Directors voted to establish the Liver and Intestine Transplant Committee to help establish and implement liver allocation and distribution policies. The distribution system for liver allografts has undergone several changes, since the original system was developed in 1987. Local preference has always been a component of organ allocation, with units of distribution being the donor service area (DSA), then the 11 UNOS regions. Level of medical urgency has also been a component of the allocation scheme. The original system was fraught with difficulty, because of the lack of agreement on definitions of the six categories of medical urgency, and the “UNOS/STAT” category that allowed bypass of the original points system. In 1994, this system was changed and those candidates with acute liver failure were given precedent over those with chronic liver disease, and the medical urgency categories for patients with chronic liver diseases simplified with waitlist time at that status playing a role in allocation. The candidates were divided into status 1 (acute liver failure), status 2A, 2B, and status 3. Even at this stage, 20 years ago, the stated objectives of equitable organ allocation were minimizing disparities (as measured by waiting times among patients with similar or comparable medical/demographic characteristics), minimizing waitlist mortality, and minimizing effects related to geography [4].

As the transplant community gained experience with this system, it became clear that the medical urgency categories (particularly with respect to status 2A, status 2B, and status 3) were too broad, lumping together patients with widely varying waitlist outcome, and depended too much on subjective criteria, with waiting time playing too large a role in organ allocation. In 1998, The US Health and Human Services published the “Final Rule” which outlined the principles that should guide the development of organ allocation policy. These included the concept that allocation policies should be based on sound medical judgment and seek to achieve the best use of donated organs, to avoid wasting organs, avoid futile transplants, and not be based on a candidate’s place of residence or listing. In October of 1999, the Institute of Medicine weighed in on recommendations to realize some of the goals of the HHS Final Rule. The implementation of the Model for End-Stage Liver Disease (MELD) score, which had originally been developed to predict survival post transjugular intrahepatic portosystemic shunt (TIPS), and subsequently shown to be a strong and reliable predictor of survival in patients with chronic liver disease [5], was the next substantial change in liver allocation policy. Status 1 patients with acute liver failure remained the highest priority patients, but the status 2A, 2B, and 3 patient categories were replaced with a more objective MELD score based on serum bilirubin, creatinine, and INR [6]. Again, concerns were raised at the time regarding the “sickest first” policy, perhaps with the unintended consequence of promoting futile liver transplants. Since this time, multiple analyses of the effect of this change in policy to utilize MELD score have been conducted. Early analyses showed a reduction in waitlist mortality and no worsening of posttransplant outcomes [7]. Subsequent analyses have documented a steady improvement in liver transplant outcome and an overall decline in waitlist mortality and time to transplantation [8] [9].

Another important concept that has been the part of discussion of resource utilization has been transplant benefit. An important contribution to the literature included the analysis of benefit which demonstrated that liver transplant benefit as measured by survival at 1 year was concentrated in those with the highest risk of waitlist death. Also, there was little, if any, benefit for liver transplant recipients with a MELD score of 14 or less, thus the policy is known as Regional Share MELD 15 [10]. Centers could not transplant a candidate with a MELD score 14 or lower if any regional candidates with MELD score 15 or higher were offered and accepted the organ offer. Notably, at that time, futile transplants among those severely ill patients were not identified for any given high MELD score, capped at a score of 40 per policy.

Distributing organs across areas larger than the DSAs began with regional sharing for status 1 patients. The effects of this change in distribution included reduced waitlist mortality for status 1 patients, reduced times to transplant, without a concomitant negative effect on other candidates on the waitlist [11] [12]. The most recent policy changes related to organ allocation include mandatory regional sharing of liver allografts to patients with MELD scores of 35 and higher (Share 35). The objective of the policy change was to increase access to livers for the sickest patients with chronic liver disease, who suffer similar or even higher waitlist mortality to status 1 patients. The Share 35 policy was proposed after studying the effects of regional sharing for status 1 patients on transplant rate and waitlist mortality.

Regional Share 35 was implemented by UNOS of 2013. An initial analysis compared liver transplant cohorts 12 months before and 12 months after implementation of the Share 35/15 allocation policies. This analysis showed an increase in the number of liver transplants (from 5523 to 5825) [13]. Findings also included an increase in MELD scores from the era before versus the era after implementation; however, MELD scores had been rising in general, before the implementation of the policy. There were no observed changes in overall patients and graft survival.

As we continue to study and learn about the imperfections in the MELD score, newly approved modifications, including the inclusion of serum sodium levels in the MELD calculation used to allocate livers, will hopefully continue to target livers to those most urgently in need. Using the MELD score to allocate liver allografts has largely fulfilled the sickest first triage algorithm, with the notable exception of the patients with hepatocellular carcinoma, and other diagnoses that qualify for "exception" points.

The effects of every policy change have been studied and these analyses may help inform future decisions that will be made regarding geographic inequity. Of course, as with any experiment that utilizes historical controls, any observed changes may either be correctly or incorrectly ascribed to a specific policy change or behavioral changes on the part of transplant centers and organ procurement organizations (OPOs) in response to the changing landscape. Other confounding and parallel changes in demographics, technical, pharmacologic, and other advances as well as unrelated differences that evolve during the two different time periods can obviously affect the observed changes. As we continue to study the effect of recently implemented changes in liver allocation, such as Share 35, we are informed by both the intended and unintended, foreseen and unforeseen consequences of such policy changes.

Should Organ Allocation Policy Consider Posttransplant Outcome?

As long as the transplant community has considered organ allocation, concerns have been brought forth and questions have been raised whether allocation policy ought to consider outcome. In the early 1990s, when those with acute liver failure originally had worse outcomes than those patients with other diagnoses [14], there were questions raised as to the utility in favoring the patients with acute hepatic necrosis.

When policy was modified to utilize the MELD score as the formula to distribute organs, similar concerns were regarding promoting futile transplants. However, based on the improving outcomes of liver transplantation with sickest first triage algorithms, it does not appear that we have reached the point of increasing futile liver transplants at this time. It is possible that because of increased scrutiny by both OPTN and the Centers for Medicare and Medicaid Services (CMS), the sickest first allocation algorithm has been tempered by risk-avoidance behavior that is promoted by the system of oversight. Transplant programs are acutely aware of their own results regarding 1- and 3-year patient and graft survival and potentially of incomplete risk adjustment. Potential flagging by either OPTN or CMS can result in significant negative consequences to the transplant center, and thus disincentivize the performance of such futile transplants. Transplant centers, on the whole, appear to be able to learn and distinguish those patients who are too sick to transplant, judging by results of 1-year graft survival, although the data may be somewhat clouded by the inclusion of patients with MELD exceptions, particularly those with HCC, who often have excellent short-term survival.

An argument has been made to consider "transplant benefit" when designing organ allocation. The limitations include a lack of a uniform definition of futility and a lack of a reliable predictive tool to forecast futility or posttransplant outcome. Whereas, MELD score is a relatively good predictor of waitlist mortality and can correlate somewhat with postliver transplant survival [15]; several studies have shown MELD score to be a relatively unreliable predictor of posttransplant outcome [16] and have advocated alternative systems to predict mortality such as SOFT, BAR, and others [17, 18]. These and others have been promoted as more accurate predictive tools, but it is unclear whether these tools would be robust enough to be used in organ allocation policy decisions.

HCC and Other Exceptions to the Rule

Liver transplantation for hepatocellular carcinoma (HCC) and priority for candidates with HCC has undergone evolution in parallel with the allocation system. The landmark paper by Mazzaferro [19••] documented that liver transplantation was effective, and if limited to candidates with smaller and fewer tumors ("Milan Criteria"), it could result in liver transplant outcomes that were similar for other diseases. To enable patients with HCC, but without a competitive lab MELD score to gain access to liver transplant organs, a policy to allow for exception points to be given was established and has been modified several times. To summarize, these revisions have been implemented to decrease the large advantage that patients with HCC are given with respect to access to liver transplant. Despite these revisions and changes, many authors document that the patients with HCC have a disproportionate advantage and increased access to liver transplants compared to other candidates [20•, 21]. In most regions, the drop-off rate for patients with HCC is lower than that of patients without HCC. The UNOS Liver Committee recently implemented a 6-month delay in the awarding of MELD exception points for patients with HCC, based on modeling that demonstrated that such a delay would equalize drop-off rates between HCC and non-HCC patients [22]. The delay also allows for a biologic test of time, where some candidates who may potentially have unfavorable outcomes posttransplant, in terms of higher recurrence rates, to drop off the list before receiving a liver transplant. The drop-off rate of candidates with HCC approaches those of candidates without HCC after waiting on the list 9–12 months. In regions that have higher MELD at transplant, and longer wait times for those candidates with HCC, the drop-off rate of HCC patients is similar to those without HCC [20•]. There are also data that support the concept that some patients with very small single HCC with favorable biology and that demonstrate complete responses to locoregional therapy have a very low drop-off rate, and probably do not merit receiving increased priority and access to liver transplant over other candidates for liver transplant [23]. This may have implications in allocation policy to lessening the priority for these candidates. It is clear that we have not yet hit the "sweet spot" of liver transplantation for HCC—that is, to prioritize transplantation for those who benefit most and have favorable outcomes postliver transplant.

There is a wide regional variation in the rate of transplants performed under MELD exceptions for other conditions in the USA [24]. As an example, in some areas of the country, up to 65 % of liver transplants are performed under exception, whereas in others, that proportion is less than 50 %. There is also large geographic variation among the 11 UNOS regions as to the characteristics of the applications, acceptance rates, and MELD scores that are awarded as well as waitlist outcomes [25]. Authors have documented the need for continuing to standardize MELD exceptions, both for HCC and other conditions. [26]. In an effort to remediate these inconsistencies in policy and practice, the UNOS Liver Committee is currently considering proposals to establish a National Liver Review Board with consistent national guidelines to be followed, to replace the current regional review board to make more consistent the MELD exception practices.

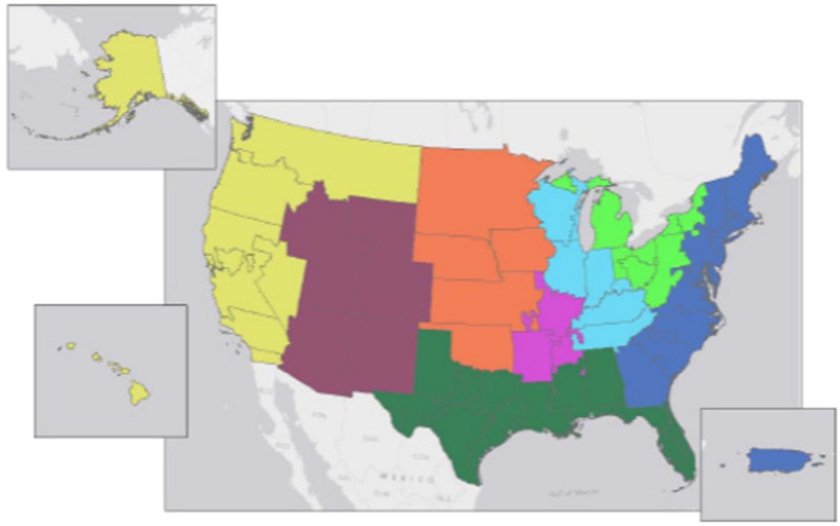
Arbitrary Geographic Boundaries Create Disparity

There are many causes of disparity in access to healthcare in general and transplantation specifically. Some of the access issues are not under the purview of transplant centers directly, such as referral patterns and the general insurance status of patients and contracts that allow or disallow patients to seek out transplantation at specific centers. Others are under the purview of the transplant centers themselves, with regard to processes of evaluation, listing practices, and organ acceptance patterns. One critical factor in creating inequity is the current organ distribution policy and is clearly caused by the lines and borders that make up the 58 DSAs and 11 UNOS regions. These areas were not designed with population sizes, donor potential, or candidates for transplantation in mind. As organ distribution is largely defined by these borders, examination of the DSAs clearly reveals that the borders distinctly separate areas with large demand for organs and areas with a relatively larger supply. There are arguments regarding the details of how we should measure demand for organs, but the organ allocation system itself can only address the patients who are waitlisted for transplantation. The supply of organs, regardless of how it is defined, e.g., actual donors, eligible donors, or total deaths in an area, varies widely, mostly dependent on death rates.

Since the mid 1990s, many authors have argued against using the arbitrary boundaries formed by the DSA/OPO borders to distribute organs [3]. As arguments for broader sharing came forward, and allocation favoring those patients with higher medical urgency and higher risk, there have been concerns about prolonging the waiting times of less urgent, lower-risk patients, and particularly if this results in transplanting patients with a worse outcome. Regional sharing (based on the existing 11 UNOS regions) was mandated for acutely ill status 1 patients and more recently, for patients with chronic liver disease with a MELD score 35 and greater. This has increased access to livers for some of the sickest patients. Despite these changes, significant geographic differences in access to livers still exist. The current DSA borders are defined in a fashion that separates areas of large demand (transplant candidates) from areas of relatively large supply (donors). Although these borders were not gerrymandered with malfeasance, the effect of these relatively confined borders is to promulgate geographic differences in access to liver transplants. That the borders of the DSA's help create geographic disparity has been recognized for over a decade. Early on, authors had noted the significant variation in OPO size, and how the practice of retaining an organ within the OPO where the organ was procured results in well-compensated patients who less urgently need a transplant being transplanted, while at the same time, a nearby poorly compensated patient would die without access to a life-saving liver transplant [3, 27]. In 1999, the IOM recommended that uniform organ allocation areas, each serving a population based of at least 9 million people, ought to be established.

The concept of redistricting is not a new one, but more recently, the UNOS Liver Committee, working with several investigators and the SRTR, has developed several alternative boundaries or districts to alleviate the disparity to access that is directly attributable and a direct result of the current boundaries [28••]. It has also become clear that simply increasing the size of the area of distribution (e.g., current 11 UNOS regions) will not automatically result in a decrease in supply/demand disparity, unless the larger areas are designed to decrease that disparity. The UNOS liver intestine organ transplant committee worked with SRTR and investigators to apply constraints and derive several optimized maps to create maps with four to eight contiguous regions that contained at least six liver transplant centers each and had a maximum average travel time of 5 h. These maps were published in a document developed by the Liver/Intestine Committee and OPTN staff [29] (Fig. 1 and Fig. 2) The SRTR recently performed a direct analysis of

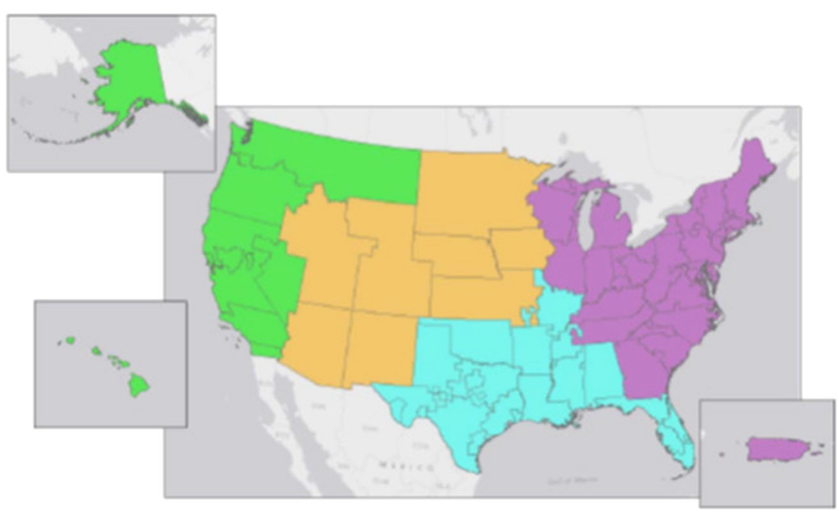
Fig. 1 Eight-contiguous district map designed to minimize supply/demand disparity (data from: Redesigning Liver Distribution to Reduce Variation in Access to Liver Transplantation, 2014, UNOS Liver and Intestinal Organ Transplantation Committee)



supply/demand by area or district, across alternative models, e.g., the current 58 DSAs versus current 11 UNOS regions versus optimized 8 and 4 district maps as described. These data are not dependent on modeling as they are based on actual data regarding donors, eligible donors, and waitlisted patients. Because of the way the current lines are drawn, the supply/demand ratio by DSA and UNOS region varies widely. In the USA, the ratio of eligible deaths/waitlisted patients is 0.27. However, the ratio of eligible deaths to waitlisted patients by DSA currently varies from highs of 2.86 in Puerto Rico and 2.14 in Mississippi, to a low of 0.11 in DSAs located in New York and Maryland. In other words, if all OPOs were to achieve a 100 % conversion rate of eligible donors, actual donors to waitlisted patients across DSAs would vary 26-fold. One can argue whether one should examine actual donors, potential donors, or all deaths, but the ratios move in parallel. The number of actual donors does depend on OPO conversion rates, and clearly, the definition of eligible donors should be refined, but the fact remains that the examination of all supply metrics appear to vary geographically, in parallel, and the greatest contributor to the variance across DSAs is not OPO performance, but potential donor deaths. The variance in these direct metrics of supply and demand is reduced by both the four and eight district models (Figs. 3, 4, 5, and 6).

Mathematical modeling, using a liver simulation allocation model (LSAM) first developed by the original US Scientific Registry of Transplant Recipients, has been instrumental in assessing the effects of policy changes by simulating the allocation of livers for transplant [30]. Most recently, an analysis utilizing a current LSAM has demonstrated that by simply utilizing the 11 UNOS regions in a full regional sharing model would paradoxically increase disparity as measured by MELD score at transplant, not decrease it. It appears that simply going to larger geographic areas would not be sufficient to decrease disparity, but rather, the actual way the borders are designed and drawn is of critical importance. Since the first analyses were performed, concerns were raised about increased travel distances and times, increased cold ischemia time, and livers

Fig. 2 Four-contiguous district map designed to minimize supply/demand disparity (data from: Redesigning Liver Distribution to Reduce Variation in Access to Liver Transplantation, 2014, UNOS Liver and Intestinal Organ Transplantation Committee)



crossing great distances for small differences in MELD scores. The increase in flying for liver allografts raised the concern of the increased costs associated with broader geographic sharing. In response to these concerns, the UNOS Liver/Intestine Committee proposed proximity circles around donor hospitals to give candidates listed at nearby transplant centers preference by awarding MELD points (e.g., 3–5 points) for those local candidates. LSAM runs predicted that the gains in disparity by adopting either a four- or eight-district map would not be eliminated by awarding these proximity points [31]. An analysis of the costs of broader sharing has been performed [32]. These data suggested that broader sharing of liver allografts can be a cost-effective strategy to reduce mortality from end-stage liver disease. There is certainly a cost to the transplant center in transplanting sicker patients, but it appears that the cost to the entire medical system may be more than offset by cost savings of caring for sick patients on the waitlist.

There are those that have argued that the areas that have good supply are largely the result of well-performing OPOs in obtaining authorization and successfully converting potential donors. The data however show that OPO performance is a fairly minor factor in driving the supply of donors, as death rates by area vary far more geographically than OPO performance. There are concerns that had been raised that implementing wider sharing with the proposed districts would result in livers being diverted from areas with better-performing OPOs to poor-performing OPOs. However, an analysis and simulations show that in fact, livers would flow from areas with high supply and lower demand to those with low supply and higher demand, not from areas from "good"

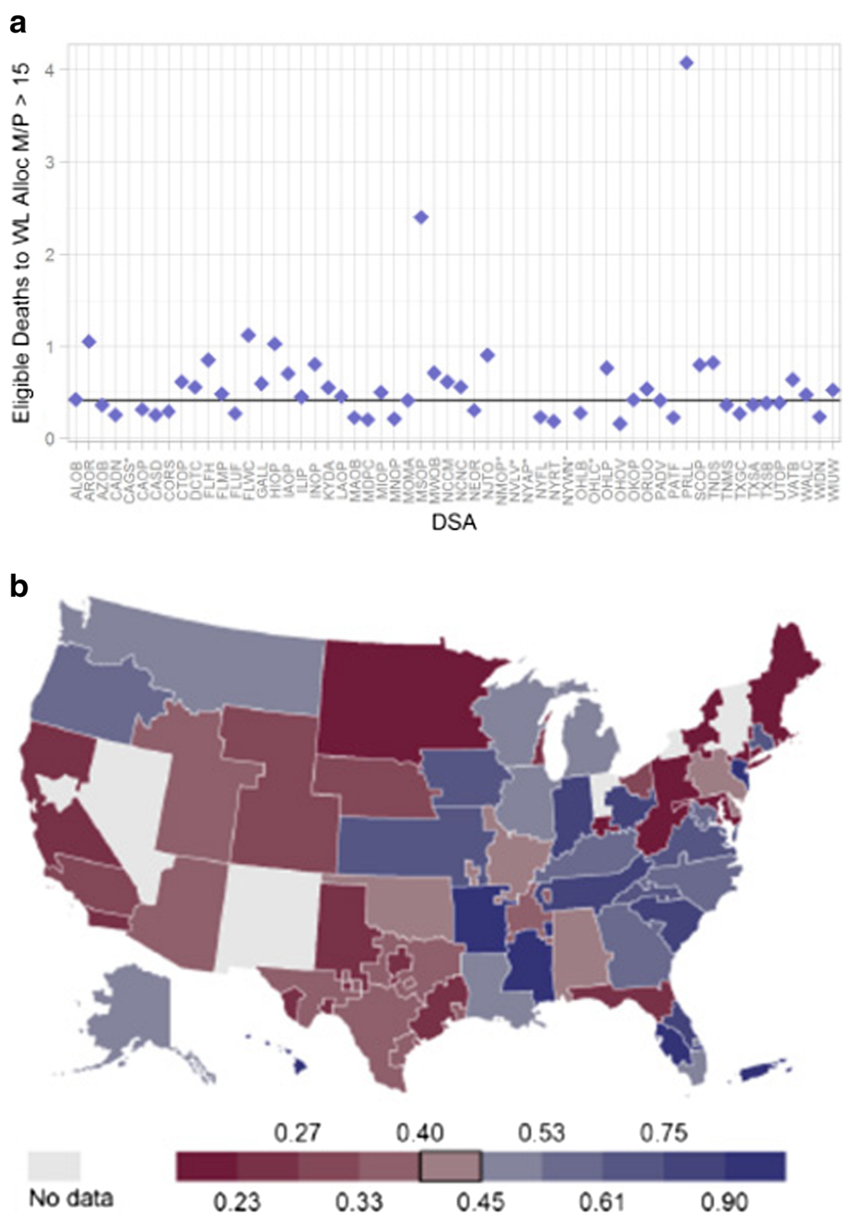
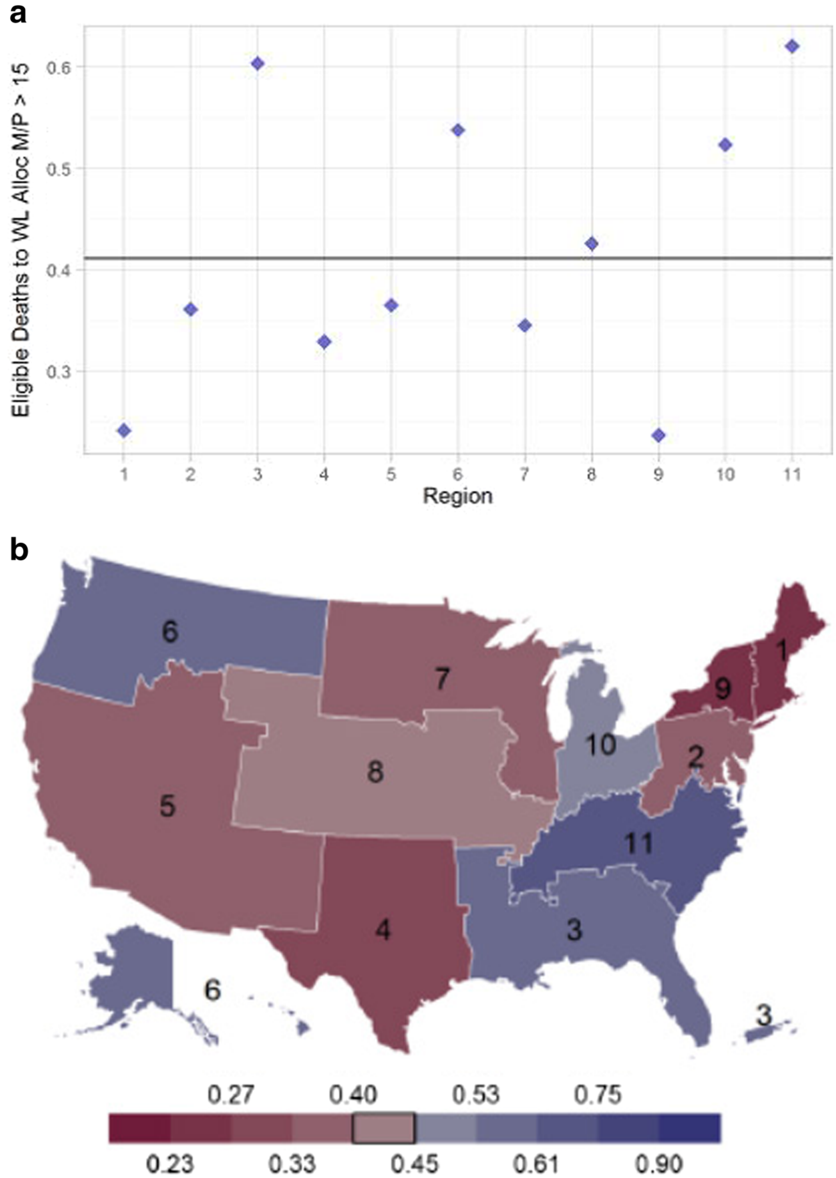


Fig. 3 Ratio of eligible deaths/waitlisted candidates with MELD >15, 2013 by DSA. Legend: x-axis = 4-letter OPO code (data from: Final analysis—OPTN Liver Intestinal Committee, Schladt, Pyke, Gentry et al. SRTR, 2015)

Fig. 4 Ratio of eligible deaths/waitlisted candidates with MELD >15, 2013 by 11 UNOS regions. Legend: x-axis = UNOS region. (Data from: Final analysis—OPTN Liver Intestinal Committee, Schladt, Pyke, Gentry et al. SRTR, 2015)



OPOs to "bad" ones. In fact, an analysis of OPO performance and DSA competition revealed that higher OPO performance was associated with more competitive DSAs [33]. Market competition was associated with increased utilization of higher donor risk kidneys and livers. Authors have stated that our efforts should be focused on increasing organ donation and increasing utilization of the existing liver donors. While there is no argument against maintaining and increasing these efforts, an analysis of the number of eligible donors and waitlisted candidates in the 58 DSAs shows that even if all OPOs were to covert 100 % of all eligible donors, the geographic disparities of supply/demand would continue to exist to a similar extent as it does presently. Also, existing data suggests that the largest potential of increasing the donor pool exists in the older and more marginal donors, which are difficult to place and presents some risk to liver transplant centers and recipients. Technologies on the horizon, such as machine perfusion and rehabilitation of liver allografts, increased use of DCD donor organs, more efficient and expedited placement of suboptimal grafts, and reducing the disincentives for the use of these organs, are all potential avenues to the increased utilization of these suboptimal donor organs. Living donor liver transplantation is utilized to a limited degree in this country. This is likely at least partially due to the uneven pressures on transplant centers to use living donors. Yeh et al. demonstrated that living donor liver transplant is predominantly performed in areas of low organ availability [34]. In fact, there is suggestive evidence that by making more even competitive pressure by eliminating the existing DSA boundaries, more organs would be procured and utilized and transplanted, therefore increasing the total number of liver transplants performed [35] .

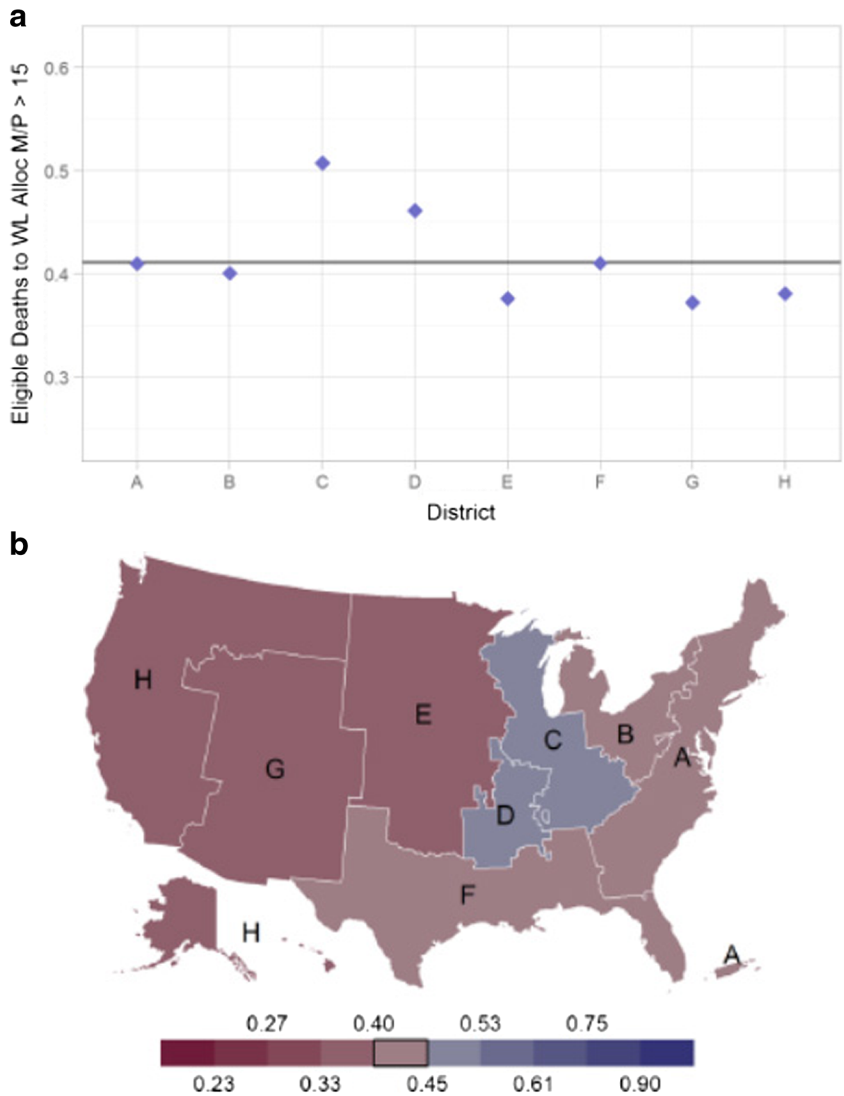


Fig. 5 Ratio of eligible deaths/waitlisted candidates with MELD >15, 2013, by eight districts (data from: Final analysis—OPTN Liver Intestinal Committee, Schladt, Pyke, Gentry et al. SRTR, 2015)

There are those that argue that by changing distribution schemes, we are simply "rearranging the deck chairs on the Titanic." This argument implies that we cannot save more lives by more equitable distribution. However, the triage of sickest first is more analogous to ordering of rescue of those victims of the Titanic that cannot swim at all before the stronger swimmers. This would result potentially in more overall lives saved as we transplant those candidates in the most urgent need before those who can potentially wait.

Can We Get it Done?

There are those that feel that the current structure, organization, and processes used to create, modify, and implement organ allocation are fundamentally flawed. UNOS, as a private, non-profit organization, is responsible for creating organ allocation policy through the OPTN contract but is still limited by political interests and conflicted parties. The governing board of directors by bylaw is at least 50 % comprised of transplant physicians and regional representatives from each of the 11 regions (which vary threefold in population and includes anywhere from 6 to 21 liver transplant programs). As such, authors have argued that OPTN/UNOS bylaws reinforce existing regional structure and the importance of regional interest [36]. Medical centers clearly feel a competitive pressure to maintain liver transplant programs that are financially lucrative and establish prestige. OPTN/UNOS, in its governance structure, and the regional representation makes it difficult to change the inequitable status quo.

With modern preservation fluid and evolving techniques, the capacity to share across broader areas clearly exists, and may increase. There are associated costs with broader sharing, but with increased trust, and a change in paradigm regarding the mechanics of organ procurement—e.g., increased use of local donor teams and with

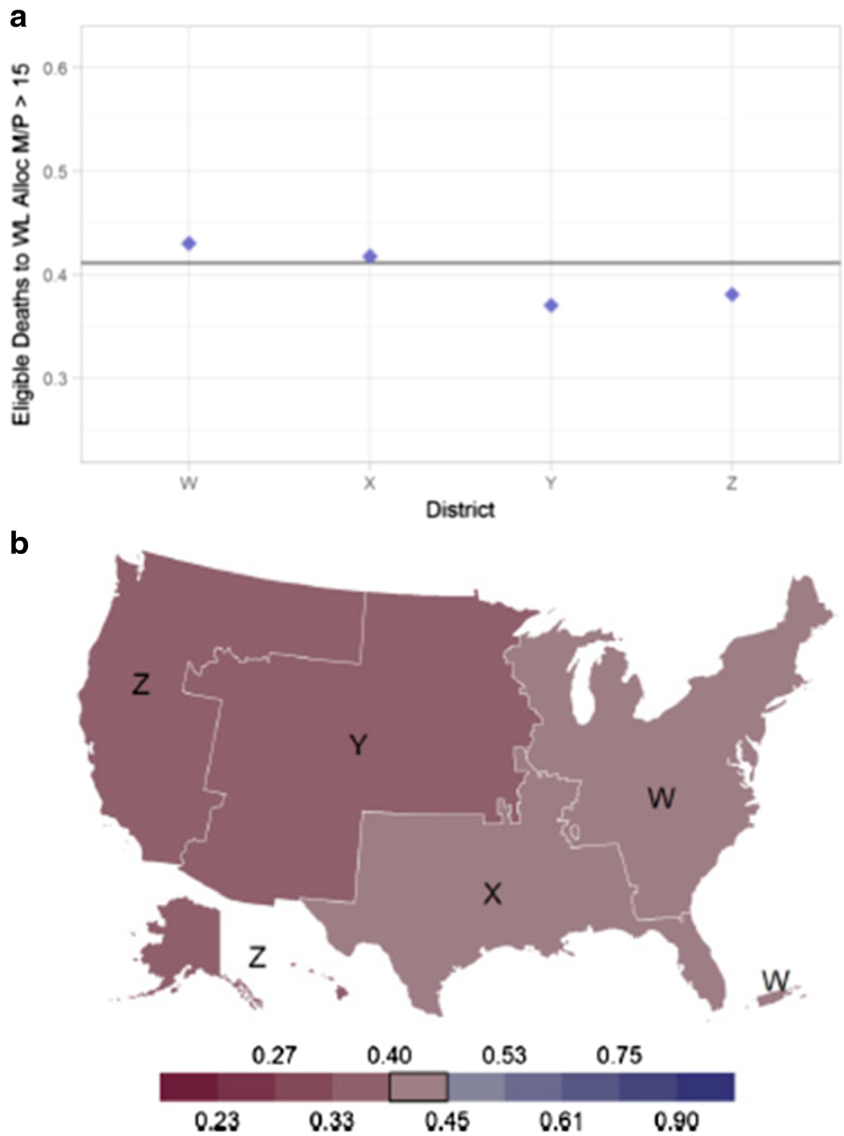


Fig. 6 Ratio of eligible deaths/waitlisted candidates with allocation MELD >15, 2013, by four districts.(data from: Final analysis—OPTN Liver Intestinal Committee, Schladt, Pyke, Gentry et al. SRTR, 2015)

increased cooperation, communication, more uniform procurement standards, and organ assessment tools, some of the logistical barriers associated with broader organ sharing can clearly be overcome. Center acceptance behavior will change with broader sharing, as it already has. In general, it appears that the better quality organs are travelling, and the higher-risk donor organs tend to be used more locally. This may influence OPO behavior and increase organ utilization. It is high time that the transplant community embrace steps to address geographic equity in access which has existed for decades, and continues to exist. Our community has done precious little to address this disparity since the HHS final rule was issued 17 years ago. The imbalance in access to liver allografts by geography in this country has resulted in a situation where those with means and favorable insurance coverage who can overcome the geographic inequities do so by traveling to areas with more favorable supply/demand as defined by arbitrary borders. Those candidates in areas of low supply/demand without means, without the option or means to travel, are condemned to stay locally.

Immediate Future Directions

To address the lack of consistency in patients awarded MELD exception points, a proposal to assemble a National Liver Review Board (NRLB) to replace the regional review boards is being developed. Included in the proposal will be guidelines that the NLRB will follow to adjudicate application for exceptions, including those for HCC. We plan a further refinement in the HCC exception system to possibly defer allocation of livers to those patients with HCC that have a low chance of drop off, incorporate alpha fetoprotein levels, and systematically allowing those patients that have tumors that are modestly beyond Milan criteria to be down-staged and transplanted. The method by which this review board will award MELD points is yet to be determined, but may be based upon the differential MELD scores that will result in transplantation based on geography. Finally, as we adjust the exception system, the geographic disparity of supply and demand that particularly affects those patients with a true lab MELD score must be addressed. The lines clearly need to be redrawn. The implementation of newly drawn districts, whether with fixed or with fluid boundaries, still needs to be sorted out and may have to proceed in a stepwise fashion.

Conclusions

As we move forward toward a more equitable liver allocation system, with respect to diseases, diagnoses, and geography, we are aided by guiding principles, past experience, analysis of implemented policy change, and mathematical modeling. The guiding principles include equitable access to life-saving and life-improving liver transplants, minimizing overall death on the waiting list, while maintaining both posttransplant survival and quality of life. As parallel efforts to reduce the gap of supply and demand continue, such as increasing organ donation, increased expediency and efficiency of placing suboptimal donor organs, molecular and cellular rehabilitation, and improvement in preservation methods of steatotic and other suboptimal livers, and ultimately engineering of transplantable organs, we must simultaneously work to correct the geographic disparity in access that is directly caused by the artificial boundaries that separate supply and demand. Until these technologic developments completely and permanently relieve the organ transplant shortage, the transplant community must continue to refine our system of organ distribution of the currently limited resource while maintaining a high level of efficiency and utility, to distribute organs equitably and serve as many of our patients as possible regardless of where they reside or what diagnosis they carry.

Compliance with Ethical Standard

Conflict of Interest Ryutaro Hirose declares that he has no conflict of interest.

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.

References

Papers of particular interest, published recently, have been highlighted as:
• Of importance
•• Of major importance

1. Scientific Registry of Transplant Recipients. 2015.
2. United Network for Organ Sharing. Available from: http://optn.transplant.hrsa.gov/converge/latestData/step2.asp.
3. Klintmalm GB. Who should receive the liver allograft: the transplant center or the recipient? Liver Transplant Surg. 1995;1(1):55–8. **discussion 80–2**.
4. Bollinger RR. A UNOS perspective on donor liver allocation. United Network for Organ Sharing. Liver Transplant Surg. 1995;1(1):47–55. **discussion 80–2**.
5. Wiesner R et al. Model for end-stage liver disease (MELD) and allocation of donor livers. Gastroenterology. 2003;124(1):91–6.
6. Coombes JM, Trotter JF. Development of the allocation system for deceased donor liver transplantation. Clin Med Res. 2005;3(2):87–92.
7. Freeman RB et al. Results of the first year of the new liver allocation plan. Liver Transplant. 2004;10(1):7–15.
8. Freeman Jr RB et al. Improving liver allocation: MELD and PELD. Am J Transplant. 2004;4 Suppl 9:114–31.
9. Austin MT et al. Model for end-stage liver disease: did the new liver allocation policy affect waiting list mortality? Arch Surg. 2007;142(11):1079–85.
10. Merion RM et al. The survival benefit of liver transplantation. Am J Transplant. 2005;5(2):307–13.
11. Humar A et al. Regionwide sharing for status 1 liver patients—beneficial impact on waiting time and pre- and posttransplant survival. Liver Transplant. 2004;10(5):661–5.
12. Washburn K et al. Regional sharing for adult status 1 candidates: reduction in waitlist mortality. Liver Transplant. 2006;12(3):470–4.
13. Massie AB et al. Early changes in liver distribution following implementation of Share 35. Am J Transplant. 2015;15(3):659–67.
14. Delmonico FL et al. The high-risk liver allograft recipient. Should allocation policy consider outcome? Arch Surg. 1992;127(5):579–84.
15. Habib S et al. MELD and prediction of post-liver transplantation survival. Liver Transplant. 2006;12(3):440–7.
16. Desai NM et al. Predicting outcome after liver transplantation: utility of the model for end-stage liver disease and a newly derived discrimination function. Transplantation. 2004;77(1):99–106.
17. Rana A et al. Survival outcomes following liver transplantation (SOFT) score: a novel method to predict patient survival following liver transplantation. Am J Transplant. 2008;8(12):2537–46.
18. Dutkowski P et al. Are there better guidelines for allocation in liver transplantation? A novel score targeting justice and utility in the model for end-stage liver disease era. Ann Surg. 2011;254(5):745–53. **discussion 753**.
19.•• Mazzaferro V. Liver transplantation for the treatment of small hepatocellular carcinomas in patients with cirrhosis. N Engl J Med. 1996;334(11):693–9. **This is a landmark article that describes Milan criteria and redefined utility of liver transplantation for hepatocellular carcinoma**.
20.• Washburn K. Hepatocellular carcinoma patients are advantaged in the current liver transplant allocation system. Am J Transplant. 2010;10(7):1643–8. **An important paper that elucidates geographic variation and differences in access to transplantation between HCC and non-HCC patients**.
21. Toso C et al. Toward a better liver graft allocation that accounts for candidates with and without hepatocellular carcinoma. Am J Transplant. 2014;14(10):2221–7.

22. Heimbach JK et al. Delayed hepatocellular carcinoma model for end-stage liver disease exception score improves disparity in access to liver transplant in the United States. Hepatology. 2015;61(5): 1643–50.
23. Mehta N et al. Identification of liver transplant candidates with hepatocellular carcinoma and a very low dropout risk: implications for the current organ allocation policy. Liver Transplant. 2013;19(12):1343–53.
24. Rodriguez-Luna H et al. Regional variations in peer reviewed liver allocation under the MELD system. Am J Transplant. 2005;5(9): 2244–7.
25. Massie AB et al. MELD exceptions and rates of waiting list outcomes. Am J Transplant. 2011;11(11):2362–71.
26. Goldberg DS, Olthoff KM. Standardizing MELD exceptions: current challenges and future directions. Curr Transplant Rep. 2014;1(4):232–7.
27. Fung JJ. Organ allocation in the United States: where does it stand? Point J Am Coll Surg. 2001;192(1):118–24.
28.•• Gentry SE. Addressing geographic disparities in liver transplantation through redistricting. Am J Transplant. 2013;13(8):2052–8. **An important paper delineating a model for redistricting to address geographic inequity**.
29. UNOS Liver and Intestinal Organ Transplantation Committee, redesigning liver distribution to reduce variation in access to liver transplantation, available at http://optn.transplant.hrsa.gov/ContentDocuments/Liver_Concepts_2014.pdf, 2014.
30. Thompson D et al. Simulating the allocation of organs for transplantation. Health Care Manag Sci. 2004;7(4):331–8.
31. Schladt DP, Pyke J, Gentry S, Schnitzler M, Israni A, Kasiske BL et al. Data request from the OPTN Liver and Intestinal Organ Transplantation Committee: Supply/Demand Ratios, Proximity Points and Additional Financial Analyses. 2015
32. Axelrod DA et al. The economic implications of broader sharing of liver allografts. Am J Transplant. 2011;11(4):798–807.
33. Adler JT et al. Is donor service area market competition associated with organ procurement organization performance? Transplantation, 2015.
34. Yeh H et al. Geographic inequity in access to livers for transplantation. Transplantation. 2011;91(4):479–86.
35. Adler JT et al. Market competition and density in liver transplantation: relationship to volume and outcomes. J Am Coll Surg. 2015;221(2):524–31.
36. Vladeck BC, Florman S, Cooper J. Rationing livers: the persistence of geographic inequity in organ allocation. Virtual Mentor. 2012;14(3):245–9.