

Article type : V - Personal Viewpoint

Agree on much, except it is time for change

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Abbreviations

DSA, donor service area

MELD, Model End Stage Liver Disease

OPOs, organ procurement organizations

Abstract

The imbalance between supply and demand of organs for transplant will not be fully solved by changes to the allocation system. Improved organ donation and utilization must be

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/AJT.15362](https://doi.org/10.1111/AJT.15362)

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accomplished through critical reassessment of OPO performance as a partnership between transplant centers, OPOs and community hospitals. The continued discussion on changes to the organ distribution system should be based on patient-centeredness, enhanced transparency, improved models and metrics. Focusing too heavily on geography without consideration for the other factors at play risks oversimplification of this complex issue.

Organ distribution is entangled in both legal and ethical debates and influenced by the financial viability of health institutions and our nation's sense of unity. As Lynch et al [1] point out, it is critical that participants in this important discussion agree on basic principles and priorities for policy development. Their core arguments are 1) Donor service area (DSA) is the cornerstone of organ availability; 2) Local placement of organs improves utilization; 3) The current role of DSA is fit for exaptation; 4) Vulnerable populations are disadvantaged by using MELD as metric for broader allocation. We will examine each of these and also put forth several tenets which are important for this discussion: 1) The metric for allocation of an organ should not be commingled with a geographic area of distribution; 2) Competition generated through increased geographic sharing is good in marketplaces and leads to increased productivity; 3) Changes to allocation policy should enhance transparency and allow for re-evaluation of models and rules used; 4) Patients should be at the center of the discussion about organ distribution rather than DSA, organ procurement organizations(OPOs) or transplant centers

It is important to understand that the debate about organ access and utilization is not new and has been ongoing since liver transplant became the primary therapy for end-stage liver disease. Twenty years ago policy makers were charged with addressing issues of allocation in liver transplantation. The Institute of Medicine was tasked by Congress to evaluate the impact of regulations on organ procurement and transplantation. The committee did not include any practicing solid organ transplant surgeons to avoid direct conflicts of interests. The report emphasized that the "system...not only has to be fair, but its fairness must be readily perceived by the public"[2]. The report also recognized that the

system “can be improved by enlarging the current organ allocation areas to include larger populations.” [2] Organ allocation based on the MELD score enabled increased transparency in the system and thus increased the perception of fairness by stakeholders. Changes in organ distribution should aim for the same.

1.1 Local (DSA) donation is the cornerstone of organ availability

The authors don't make a clear argument here. Certainly the relationship between OPOs and hospitals within a DSA is critical to conversion of potential donors to actual donors. However, the authors fail to acknowledge that the primary driver of organ availability is the incidence of eligible deaths in the population relative to the prevalence of end organ disease [3]. Efficiency and effort of hospital staff and OPOs increase donation, but the benefit of those efforts is not exclusively local. (See Figure 1). Their argument comparing the performance of two OPOs does not support their argument.

1.2 Ultra-local (center) utilization converts potential to reality

We should remove the modifier ultra-local, as any utilization converts potential to reality. The variance in utilization between programs within a DSA does not contradict that disparity is a feature of geography and policy. The authors acknowledge the example of Texas but fail to note that patients in Fort Worth are transplanted at a significantly higher MELD than patients thirty miles away in Dallas. Eleven of the 58 OPOs are not contiguous, skipping counties and patients (See Figure 2). There are many examples but recent data published by UNOS show that in Milwaukee the MMaT (Median MELD at Transplant) was 35 while in the same state patients in another DSA had MMaT of 30. This represents a significant difference in access

(https://optn.transplant.hrsa.gov/media/2812/mts_distribution_document.pdf).

1.3 The current role of DSA is fit for exaptation

Lynch et al argue DSAs are fit for exaptation; although not intended to define limits for organ distribution, they currently apply to practice patterns and align with state borders and are therefore appropriate units of distribution. Exaptation is the idea that one trait is repurposed for another to play another role. In one of the earliest papers, about exaptation, Gould and Vrba

argued that a trait often required significant new adaptations to better fill its new role[4]. For example, calcium phosphates laid down in the skin of early vertebrates for storing phosphates were changed in a substantial way to become bone and function of support. The example of exaptation used by Lynch et al, the transformation of feathers in primitive birds into the feathers useful for flight in modern birds took millions of years of changes and evolution. The fact that a system or trait can be repurposed does not mean the same, as it is the best system for that purpose. We believe our community can imagine a more efficient process for organ distribution than exaptation of DSA.

1.4 Vulnerable populations are disadvantaged by using MELD as metric for broader allocation

Lynch et al further argue that vulnerable populations are disadvantaged by using MELD as metric for broader allocation. We agree with the authors that the sickest patients are those at highest risk of dying from their liver disease, and the vulnerability of patients living a long distance from their transplant center or in an area with a high Community Health Score (CHS) has merit[5]. As they point out, both are independently associated with increased mortality. We agree that policies should consider the impact on disadvantaged populations.

The metric for allocation of an organ should not be comingled with geographic area of distribution.

We agree that the performance of the OPOs within a DSA can influence organ availability, and OPOs have a critical task in increasing organs available for transplant. OPOs without a local liver program still generate liver donations for transplant by sharing outside their DSA. The authors further state that variability in organ availability is demonstrated by regional differences in the median meld at transplant (MMAT). We would argue that the variability of the MMAT around the country reflects differences in both the supply and demand of organs. Even with equivalent organ supply, variability would persist based on prevalence of liver disease and population density. Given the differences in demand, shouldn't patients with similar risk of pre-transplant mortality have equal access to life saving organs? By overlaying issues of supply and demand the authors obfuscate the metrics of disease severity for organ allocation. MMAT can be influenced by surgical practices, including the ability to successfully add patients to the waitlist

and use of marginal organs for patients with lower MELD scores. MELD has undergone addition of sodium to improve capture of pre-transplant mortality risk[6]. Exceptions points have undergone many changes and are scheduled to significant changes in the coming year. While allocation/distribution policies and OPO efficiency both contribute to saving lives for patients with liver disease, the two should not be conflated as they are separate challenges with separate solutions.

Competition generated through increased geographic sharing is a good and leads to increased productivity.

We agree that successful transplantation requires center willingness, but utilization-or willingness-is increased with the addition of a competing center. While individual centers may differ in their selection criteria for age, quality, etc., the relationship between competition and organ transplantation bends towards increased competition. Increasing geographic sharing increases competition[7, 8] and has the potential to improve utilization of organs and OPO performance by allowing the OPOs to be more aggressive in placement of organs.[9] Regional sharing has resulted in increased liver transplants, fewer discards, and lower waitlist mortality as well as increased organ utilization by OPOs, particularly of marginal allografts [10]. Similarly, competition among transplant centers within a DSA has been shown to lead to increased utilization of higher risk organs[11]. As the authors point out post-transplant survival is not necessarily negatively impacted by increased organ utilization, and increased volume at aggressive centers likely allows use of higher risk organs without significant effect on overall graft and patient survival[12]. Prior work has modeled geographic density along with market competition to describe the associations between market competition, geography, transplantation volume, and outcomes [9, 13]. Rather than abandon the idea of increased sharing, we propose further work is needed in this area to develop policies that increase demand for marginal livers, and adjustment of SRTR models for OPO performance to incorporate market competition.

Changes to allocation policy should enhance transparency and allow for re-evaluation of models and rules used.

Using variables that are easily understood enhances evaluation and transparency. As the

IOM stated twenty ago, the perception of fairness is critical. Few argue that the system today is easily understood by patients or providers. A system where organs are distributed over a defined distance is both measurable and modifiable.

Policies to improve organ donation rates, increase accuracy of metrics for allocation, introduction of competition into the markets and standardize waitlist practices may be more effective if pursued in parallel rather than series, with improvement in one aspect expected to ultimately lead to some change in the others.

Patients should be the center of the discussion about organ distribution rather than DSA, OPOs or transplant centers.

The barriers to high quality care experienced by vulnerable and disadvantaged populations are multifaceted. It is tempting when designing policy to try to fix multiple needs of an underserved population. [3] Distance from a transplant center has been shown to negatively influence outcomes, but increased geographic sharing is neither the cause of nor solution to this problem. Furthermore, the Community Health Score is an indicator of population vulnerability influenced by numerous factors other than geographic location including race, income, education level, health literacy, nutrition, etc. While CHS may be associated with waitlist mortality, changes to organ distribution policy will not necessarily improve the overall health of these vulnerable communities. One route to improving access to liver transplant may be improving the metric for broader allocation, in this case MELD, so as to more accurately reflect waitlist mortality rather than maintain an unbalanced and inequitable system. For patients to remain at the center of the debate, the fundamental principle must remain to transplant the sickest patients first. A patient centered policy would not leave behind the 94.5% patients who list in their DSA due to Medicaid boundaries[1]. It is equally important to avoid making the issues so complex and overlapping that inequalities in the current system are maintained due to fear of change. This is neither transparent nor easily re-evaluable. We urge the adoption of policies that are both. Otherwise, we find ourselves just supporting the status quo over any change.

Conclusions

Lynch et al make several strong points. We agree metrics for organ allocation should

be objective and minimize unacceptable consequences across other domains. Improvement in DSA and OPO performance is a critical part of improving access to transplantation for patients, and clearly there is room to improve our utilization of organs within the current system. However, although incentives to increase organ donation may be instituted and communicated locally, the burden of this task should be shared by all members of the transplant community with the primary goal of protecting patients, who should not be held responsible for poor performing OPOs. In addition, we must realize that our process for the recovery and transport livers is evolving, and both increased travel by recovery teams and increased use of local teams are likely inevitable. Rather than abandon efforts to improve regional and national distribution of organs, we should make better use of the substantial data and talent within the transplant community to develop and iteratively model innovative approaches that account for population density, care standardization, aberrant geography, socio-economics, access to transplantation, and local community engagement in organ donation.

Disclosure

The authors of this manuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation*.

Figure legends

Figure 1. Location of centers transplanting kidneys procured by Life Link of Georgia (GALL) from 7/1/2017 to 6/30/2018

Figure 2. Non-contiguous organ procurement organizations in Ohio (A) Illinois/Missouri (B) Mississippi/Tennessee/Arkansas (C) and Wisconsin (D)

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Figure 1.

Figure E3. Programs transplanting kidneys procured by GALL, 07/01/2017 to 06/30/2018*



Figure 2

