

BRIEF COMMUNICATION

Dynamic impact of liver allocation policy change on donor utilization

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Liver allocation policy was changed to reduce variance in median MELD scores at transplant (MMaT) in February 2020. "Acuity circles" replaced local allocation. Understanding the impact of policy change on donor utilization is important. Ideal (I), standard (S), and non-ideal (NI) donors were defined. NI donors include older, higher BMI donors with elevated transaminases or bilirubin, history of hepatitis B or C, and all DCD donors. Utilization of I, S, and NI donors was established before and after allocation change and compared between low MELD (LM) centers (MMaT \leq 28 before allocation change) and high MELD (HM) centers (MMaT $>$ 28). Following reallocation, transplant volume increased nationally (67 transplants/center/year pre, 74 post, p .0006) and increased for both HM and LM centers. LM centers significantly increased use of NI donors and HM centers significantly increased use of I and S donors. Centers further stratify based on donor utilization phenotype. A subset of centers increased transplant volume despite rising MMaT by broadening organ acceptance criteria, increasing use of all donor types including DCD donors (98% increase), increasing living donation, and transplanting more frequently for alcohol associated liver disease. Variance in donor utilization can undermine intended effects of allocation policy change.

KEYWORDS

donor risk, donor risk index, donor utilization, geographic disparities, liver allocation, liver allocation policy, liver redistribution, liver redistricting, marginal donors, median MELD at transplant, MMaT, non-ideal donors

1 | INTRODUCTION

Liver allocation policy in the United States changed on February 4, 2020^{1,2}. Acuity circles replaced donation service areas (DSAs) as the geographic determinant in allocation and broad sharing replaced a

predominantly local distribution system.³ Lawsuits⁴ filed by wait-listed transplant candidates argued that probability of receiving a transplant should not depend on DSA boundaries and litigation drove national policy change. In liver transplantation, differences in median MELD score at transplant (MMaT) between centers came

Abbreviations: ALD, alcohol-associated liver disease; DCD, donation after circulatory death; DSA, donor service area; HM, high MELD center; I, ideal donor liver; LDRI, liver donor risk index; LM, low MELD center; MELD, model for end-stage liver disease; MMaT, median MELD at transplant; NI, non-ideal donor liver; NLRB, national liver review board; OPO, organ procurement organization; OPTN, organ procurement and transplantation network; S, standard donor liver; STAR, standard transplant analysis and research; UNOS, United Network for Organ Sharing.

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under scrutiny. Broader sharing was predicted to at least partially reduce variance in MMaT.⁵ Predictive models could not, however, address the broad array of behavioral changes likely to occur in response to new policy.

Debate preceding allocation change was heated. Proponents argued that broader sharing was necessary and consistent with the Organ Procurement and Transplantation Network (OPTN) Final Rule⁶ which mandates that allocation of organs “shall not be based on the candidate’s place of residence or place of listing.”⁷⁻¹¹ Opponents disputed OPTN methodology^{12,13} and predicted that broader sharing would lengthen procurement travel, prolong ischemic times, and escalate cost.^{8,14,15} Others argued that differences in MMaT between centers are rooted in varied organ procurement organization (OPO) efficiency, and feared broader sharing would not incentivize low-performing OPOs to improve.^{14,16,17} Still others argued that access to care varies in urban and rural areas and that broader sharing would disadvantage healthcare-poor populations.¹⁸ Nonetheless, with threat of external interference looming, the transplant community settled upon acuity circles as a path forward.

Significant time has passed since allocation policy change was implemented, four post-policy change interim analyses¹⁹⁻²² have been completed, and continuous reassessment is appropriate. Use of every viable donor liver remains a top priority within the transplant community, and it is therefore essential to evaluate the dynamic interplay between policy change and donor utilization. Our national analyses emphasize whether a given transplant center had a MMaT above or below the national median prior to allocation change and critically examine the effect of policy change on center behavior as reflected in donor utilization.

2 | METHODS

Liver transplants performed between February 4, 2017 and June 30, 2021 were identified in UNOS STAR files. Centers performing <20 liver transplants per year were excluded. Adult living and deceased donor transplants aged ≥ 18 were included. Simultaneous liver-kidney transplants and all other combined organ transplants were included. Status 1 recipients were included.

The three-year time period from February 4, 2017 to February 3, 2020 was used as a baseline for pre-allocation policy change behavior. Transplants from February 4, 2020 to June 30, 2021 were used to quantify post-allocation change behavior. Using MMaT data published by UNOS and current on February 4, 2020 centers were classified as high MELD (HM) if the center MMaT was $>$ than the national median of 28 at that time. Centers with MMaT ≤ 28 were classified as low MELD (LM). Center transplant volume was calculated for the pre- and post-eras and normalized to a yearly rate. Change in MMaT was calculated as the difference between center MMaT on February 4, 2020 and center MMaT as listed by UNOS September 10, 2021. Definitions of ideal (I), standard (S), and non-ideal (NI) donor livers were formulated using clinical and laboratory data available for all donors. Definitions are intended to reflect surgeons’ perceptions

of donor quality at the time of organ offer. Center-level patterns of usage of I, S, and NI livers were calculated pre- and post-policy change. Offer acceptance ratios were extracted from publicly available SRTR data. Timeframes defining COVID “eras” were identical to those used by the SRTR in interim analyses.^{19,21}

Separate Poisson models with a repeated measures effect for center were fit to test for significant differences within seven subsets of the data: (1) normalized annual transplant volume, (2) use of I, S, and NI donor livers, (3) living donor use, (4) DCD use, (5) MELD exception, (6) HCC, and (7) alcoholic liver disease. Model (2) had fixed effects for center classification (HM, LM), allocation (pre, post), donor criteria (I, S, and NI), and the three-way interaction. Models (1) and (3) through (7) had fixed effects for center classification (HM, LM), allocation (pre, post), and the two-way interaction. To analyze COVID effects on transplant volume an additional Poisson model was fitted to normalized monthly volumes with a repeated measures effect for center, fixed effects for time frame (pre COVID, COVID onset, and COVID stabilization) and center classification (HM, LM), and the two-way interaction. Lastly, for analyses involving offer acceptance ratios, a regression model was fitted to the acceptance ratio with a repeated effect for center and fixed effects for center classification (HM, LM), allocation (pre, post), and the two-way interaction. Acceptance ratios included seven timeframes from June 30, 2016 to December 31, 2020. SAS 9.4 (Cary, NC) was used throughout.

3 | RESULTS

A total of 23,428 liver transplants were performed at 116 transplant centers over the 3 years preceding allocation change. There were 12,049 transplants performed at 116 centers in the 18 months following allocation change. On February 4, 2020 the national MMaT was 28. Fifty-eight centers (44.3%) had a MMaT > 28 and are classified as high MELD (HM) centers, while 73 centers (55.7%) had a MMaT ≤ 28 and are classified as low MELD (LM) centers (Table 1). To date, the overall average MMaT has stayed the same for HM centers and increased by 1.6 for LM centers. Nationally, annualized transplant volume increased in the post-era (67 transplants/center/year pre, and 74 transplant/center/year post, $p = .0006$). Change in transplant volume was highly significant for the subset of transplant centers designated HM centers ($p = .0007$) and less so for the subset designated LM centers ($p = .035$).

To examine the effect of COVID on transplant volume the 4.5 years of our study were divided into pre-COVID, COVID onset, and COVID stabilization eras using date ranges defined by the SRTR in their interim analyses of allocation change. Within these definitions, the COVID onset era reflects the time period in which the pandemic was thought to have most significantly disrupted transplantation. In aggregate, neither LM nor HM centers showed significant changes in transplant volume during the COVID onset era (Table 2). Regression analyses did identify 18 individual transplant centers that had significant changes in transplant volume during

this time. Seven centers (3 HM, 4 LM) experienced an increase in transplant volume and eleven centers (5 HM, 6 LM) experienced a decrease in volume.

Definitions of ideal (I), standard (S), and non-ideal (NI) donors are provided in Table 3. NI donor livers were allocated at higher sequence numbers in match runs, were more frequently discarded, and were more commonly associated with primary non-function. Median recipient MELD was lowest for recipients of NI donor allografts. Inclusive of all transplants in the study, 5145 (14.5%) were performed with I donors, 13,232 (37.3%) were performed with S donors, and 17,100 (48.2%) were performed with NI donors. There were no significant changes in the composition of the donor pool in the pre- and post-eras.

Following allocation change, HM centers significantly increased use of I and S donor livers (I = 10.6 tx/cntr/yr pre, 12.5 post, $p < .0082$; S = 25.7 pre, 29.7 post, $p = .0003$) but not NI donor livers (32.6 pre, 34.3 post, $p .2$). In contrast, LM centers saw small decreases in use of I and S donor livers (I = 9.3 tx/cntr/yr pre, 9.0 post, $p .8$; S = 25.2 pre, 25.0 post, $p 0.8$) and significantly increased use of NI livers (31.8 pre, 38.1 post, $p = .0005$) (Figure 1). Nationally, there was an increase in NI liver use (32.1 pre-, 36.4 post-, $p = .0005$).

Living donor transplantation is more commonly utilized at HM centers and DCD allografts are more commonly transplanted at LM

centers. Following allocation change LM centers increased use of both living donor grafts (2.2 tx/cntr/yr pre, 3.2 post, $p 0.005$) and DCD donors (5.4 pre, 9.2 post, $p < .0001$). At HM centers rates of living donor and DCD utilization were not significantly different following allocation change. In the post era, both HM and LM centers displayed sharp decreases in the number of transplants performed for recipients with MELD exception points, and both types of centers displayed significant increases in number of transplants performed for patients with alcohol-associated liver disease (ALD). Organ offer acceptance ratios rose for LM centers (1.2 pre, 1.3 post, $p = .05$) and dropped for HM centers (1.2 pre, 1.0 post, $p = .0003$).

Center-level analysis of change in MMaT by change in transplant volume (Figure 2A) reveals that centers segregate into three distinct categories. Thirty-nine centers (Type I centers) have experienced a rise in transplant volume with MMaT unchanged or decreasing, and of these 71.8% are HM centers. Another 33 centers (Type II) demonstrate increasing transplant volume despite increasing MMaT, and 81.8% of these centers are LM centers. An additional 41 centers (Type III) have experienced a decrease in transplant volume with MMaT unchanged or increasing, and 65.9% of these centers are LM centers. The geographic distribution of transplant centers by type (Figure 2B) reveals that HM and Type I centers are predominantly located in areas of higher population density whereas LM and Type

TABLE 1 Comparative analysis of high MELD and low MELD centers

	Low MELD (LM) centers (n = 65)				High MELD (HM) centers (n = 51)			
	Pre	Post	Δ	p value	Pre	Post	Δ	p value
MMaT	26.1	27.7	1.6		30.3	30.3	0	
Annual transplant volume ^a	61.5	67.0	5.5	.0345	65	72.3	7.3	.0007
Ideal donor volume	9.3	9.0	-0.3	.7566	10.6	12.5	1.9	.0082
Standard donor volume	25.2	25.0	-0.2	.8444	25.7	29.7	4	.0003
Non-ideal donor volume	31.8	38.1	6.3	.0005	32.6	34.3	1.7	.2251
Living donor volume	2.2	3.2	1.0	.0048	3.9	4.1	0.2	.6525
DCD volume	5.4	9.2	3.8	<.0001	3.9	4.3	0.4	.3654
MELD exception volume	14.6	8.8	-5.8	<.0001	20.0	14.7	-5.3	<.0001
HCC volume	8.9	6.4	-2.5	<.0001	12	10.7	-1.3	.1645
Alcoholic hepatitis volume	16.5	23.7	7.2	<.0001	18.1	27.2	9.1	<.0001
Organ offer acceptance ratios	1.2	1.3	0.1	.0521	1.2	1.0	-0.2	.0003

^aVolumes are reported as mean number of transplants per center per year.

TABLE 2 COVID effect by center type

	Mean monthly volume (% change)			p-value	
	Pre COVID	COVID onset	COVID stabilization	Pre versus onset	Pre versus stabilization
Low MELD (LM) centers	5.9	5.9 (0.0)	6.6 (11.9)	.1461	.0196
High MELD (HM) centers	5.6	5.7 (1.8)	6.3 (12.5)	.3133	.0033

	Ideal	Standard	Non-Ideal
Definition^a			
Age	≤40	40 < age < 60	≥60
BMI	≤25	25 < BMI < 35	≥35
DCD	no	no	yes
Peak bilirubin	≤2	≤2	>2
Peak AST	≤500	500 < peak AST < 2000	≥2000
Peak ALT	≤500	500 < peak ALT < 2000	≥2000
HBc Ab	neg	pos	pos
HBV NAT	neg	neg	pos
Anti-HCV	neg	pos	pos
HCV NAT	neg	neg	pos
Organ Type	whole	whole	split
Survival	living	deceased	deceased
Characteristics			
Recipient MELD; median (Q1-Q3)	23 (14-33)	27 (17-35)	21 (14-29)
Match Run Sequence # at which the liver was placed; median (Q1-Q3)	5 (2-12)	5 (2-11)	8 (3-24)
# Recovered; count	4575	14 391	20 663
# Transplanted; count (%)	4480 (97.9)	13 730 (95.4)	17 804 (86.2)
# Discarded; count (%)	95 (2.1)	661 (4.6)	2859 (13.8)
PNF rate per 1000 Tx	7	10	11

TABLE 3 Definitions and characteristics of standard, ideal, and non-ideal donor livers

^aAll living donor grafts are classified as ideal. All DCD grafts are classified as non-ideal. For the remaining parameters, a single value outside of the ideal range prohibits classification as ideal, and a single value outside of the standard range prohibits classification as standard.

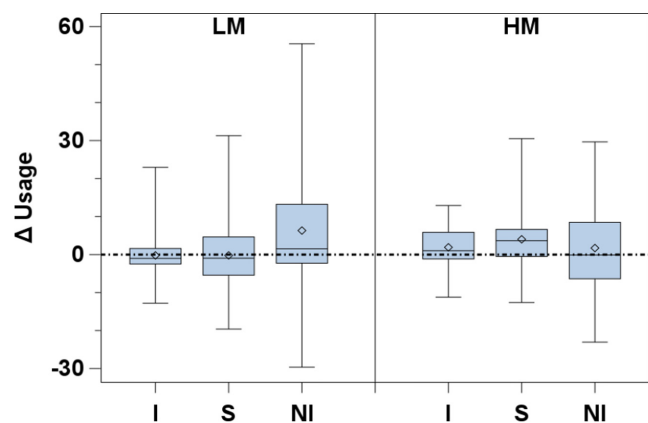


FIGURE 1 Ideal (I), standard (S), and non-ideal (NI) donor liver usage for high MELD (HM) and low MELD (LM) transplant centers. Change in usage was calculated as the average per-center 12-month volume difference from pre to post in utilization of I, S, and NI donor livers in the 3 years preceding liver allocation policy change versus the first 18 months following policy change. Error bars reflect the minimum and maximum change in usage. Horizontal lines reflect median values and diamonds reflect mean values [Color figure can be viewed at wileyonlinelibrary.com]

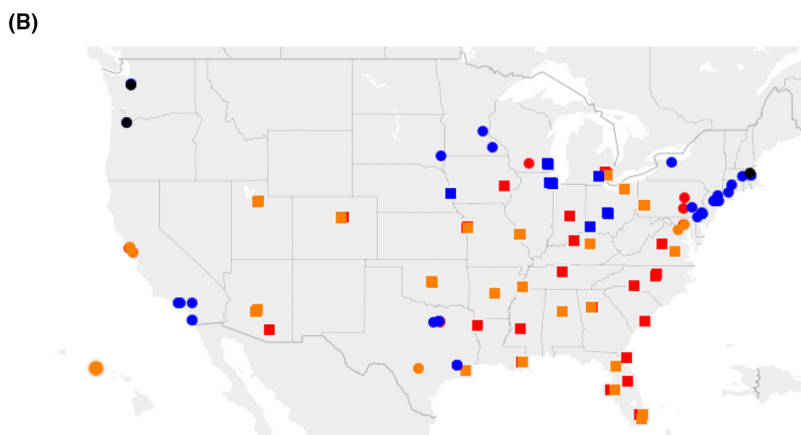
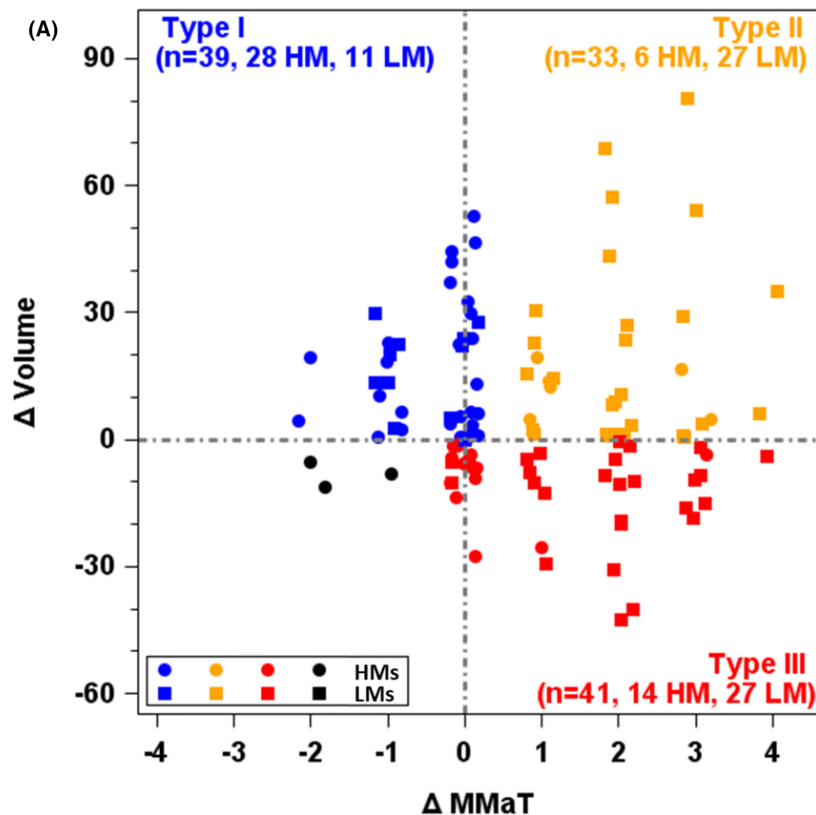
II and III centers are more commonly located in regions of lesser population density.

Characteristics of Type I, II, and III centers are shown in Table 4. Type I centers display increasing annual transplant volume despite a declining MMat, static organ offer acceptance ratios, and increases in use of donor allografts of all types (Figure 3). Type II centers demonstrate an increase in annual transplant volume despite a paradoxical increase in MMat. Type II centers showed prominent increases in NI liver use (37.5% increase), living donor use (61% increase), DCD use (98% increase), and increased rates of transplantation for alcohol associated liver disease (76.8% increase). Organ offer acceptance ratios rose at Type II centers. Type III centers demonstrate loss of transplant volume, decreased donor utilization, and dropping offer acceptance ratios.

4 | DISCUSSION

Variance in MMat across DSAs was interpreted as geographic inequity in access to transplantation and became the rationale for the OPTN and UNOS to eliminate DSAs and introduce acuity circles.^{2,23}

FIGURE 2 (A) Transplant centers with MMaT > than the national median prior to allocation policy change are termed HM centers and are denoted with circles. Centers with MMaT ≤ the national median prior to allocation change are termed LM centers and are denoted with squares. Change in MMaT was calculated as the difference in MMaT prior to February 4, 2020 and on September 10, 2021. The 3-year time period from February 4, 2017 to February 4, 2020 was used to calculate a per-center average 12-month transplant volume prior to allocation change, and the 18 months following allocation change we used to calculate an average per-center 12-month transplant volume. Transplant centers with increasing transplant volume and decreasing or unchanged MMaT are termed Type I centers. Centers with increasing MMaT and increasing transplant volume are termed Type II centers. Centers with increasing or unchanged MMaT and decreasing volume are termed Type III centers. (B) Geographic distribution of transplant centers by type



SRTR modelling predicted variance in DSA-level median MELD/PELD at transplant to drop with acuity circles.⁵ To date, there have been four interim analyses. Chyou et. al.²⁰ published a 6-month report and found no significant change in MELD variance. The OPTN Liver and Intestinal Transplantation Committee issued 1-year and 15-month monitoring reports^{19,21} concluding that “there have been decreases in the variance of MMaT by OPTN Region, DSA, and state, though these were not statistically significant.” Wey et. al.²² show that allocation change has resulted in increased access to liver transplantation for candidates with MELD/PELD scores of 29 or higher and increased use of DCD allografts for recipients with MELD/PELD scores 15–28. All reports refrain from classifying centers based on MMaT relative to the national median prior to policy change. Our data show fundamentally different behavioral responses to allocation policy change by LM and HM centers.

To investigate center-level responses to allocation policy change, we examined utilization of donor organs of varying quality. We formulated broad classifications of donor livers as ideal, standard, and non-ideal using data available at the time of organ offer and considered by liver transplant surgeons in their decision making. We acknowledge that these classifications are new and posit they reflect common surgical judgment. Our classifications bear resemblance to the liver donor risk index (LDRI)²⁴ but incorporate variables such as donor hepatitis C status which now weigh heavily in the consideration of organ offers. NI livers were more frequently discarded and transplanted into lower MELD recipients deeper within match runs suggesting that accepting surgeons felt need to balance donor and recipient risk. Notably, 48.2% of livers used for transplantation were NI highlighting the immense number of lives saved using donor livers perceived to have some element of increased risk.

TABLE 4 Comparative analysis of Type I, II, and III centers

	Type I centers (n = 39)				Type II centers (n = 33)				Type III centers (n = 41)			
	Pre	Post	Δ	% change	Pre	Post	Δ	% change	Pre	Post	Δ	% change
MMA _T	29.9	29.5	-0.4		26.5	28.5	2.0		27.1	28.5	1.4	
Annual transplant volume ^a	64.2	80.8	16.6	25.9	63.2	82.1	18.9	29.9	75.0	63.6	-11.4	-15.2
Ideal donor volume	9.6	11.2	1.6	16.7	10.3	13.0	2.7	26.2	9.9	8.2	-1.7	-17.2
Standard donor volume	24.4	30.2	5.8	23.8	23.3	28.4	5.1	21.9	28.4	23.9	-4.5	-15.8
Non-ideal donor volume	30.2	39.3	9.1	30.1	29.6	40.7	11.1	37.5	36.7	31.5	-5.2	-14.2
Living donor volume	3.0	3.1	0.1	3.3	4.1	6.6	2.5	61.0	2.4	2.3	-0.1	-4.2
DCD volume	4.4	6.6	2.2	50.0	4.9	9.7	4.8	98.0	6.0	7.2	1.2	20.0
MELD exception volume	18.1	14.9	-3.2	-17.7	16.2	11.7	-4.5	-27.8	19.9	10.3	-9.6	-48.2
HCC volume	10.8	10.6	-0.2	-1.9	10.3	8.3	-2.0	-19.4	11.8	7.9	-3.9	-33.1
Alcoholic hepatitis volume	17	28.1	11.1	65.3	15.5	27.4	11.9	76.8	19	21.3	2.3	12.1
Organ offer acceptance ratios	1.1	1.1	0	0.0	1.2	1.3	0.1	8.3	1.2	1.1	-0.1	-8.3

^aVolumes are reported as mean number of transplants per center per year.

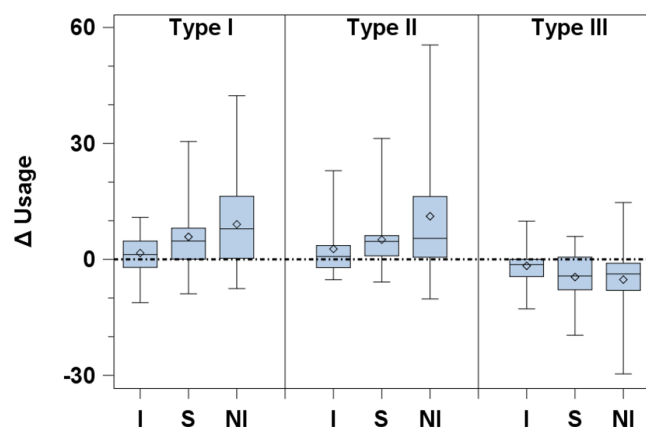


FIGURE 3 Ideal (I), standard (S), and non-ideal (NI) donor liver usage for Type I, II, and III transplant centers. Change in usage was calculated as the average per-center 12-month volume difference from pre to post in utilization of I, S, and NI donor livers in the 3 years preceding liver allocation policy change versus the first 18 months following policy change. Error bars reflect the minimum and maximum change in usage. Horizontal lines reflect median values and diamonds reflect mean values [Color figure can be viewed at wileyonlinelibrary.com]

Allocation policy change established a “Robin Hood” type of liver redistribution in which “donor poor” regions were predicted to see an increase in transplant volume and “donor rich” regions would, at least temporarily, become net exporters of donor livers. Our data demonstrate a rise in national volume that was achieved in different ways across centers. HM centers have capitalized on influx of I and S donor livers to increase transplant volume. Rates of DCD and living donor use have remained static and organ offer acceptance ratios have dropped at HM centers. In contrast and in order to continue serving the needs of waitlisted patients, LM centers have displayed an aggressive phenotype with increasing offer acceptance ratios and increased use of NI and DCD donors. While an overall increase in national transplant volume is encouraging, a net increase in national MMA_T is worrisome.

Numerous studies support use of every “transplantable” organ; however, complication rates rise as donor quality decreases.^{25–27} Patients want equal access to transplant and deserve equal access to high-quality donor organs. Monitoring usage of all donor types will be important as behavioral responses to allocation change evolve. Preliminary data suggest no increase in mortality associated with allocation change¹⁹ and it is very unlikely that NI donor use has been pushed to a limit where risk exceeds benefit. The ability of adapting centers to increase NI liver usage raises an important question. Did past variance in MMA_T reflect geographic disparity or center-level differences in willingness and ability to use every “transplantable” donor liver? The answer is no doubt confounded by variance in OPO efficiency, burden of liver disease by locale, and access to pre-transplant care; however, the notion of “donor poor” regions is too simplistic.

While the stated goal of allocation policy change was to reduce variance in MMA_T, four studies^{19–22} show that this has not occurred. Wey and colleagues²² hypothesize that variance in MMA_T remains unchanged because “offer acceptance practices have significant variation across transplant programs and are associated with MMA_T across DSAs. Acuity circles could reduce the effect of donor supply and demand on MMA_T, but not the effect of offer acceptance practices.” Our data support this hypothesis. LM and HM centers are not equally maximizing the available donor pool. While it does make sense for allocation policy to direct the highest quality organs to the sickest candidates, aggressive acceptance practices can reduce overall center acuity. Equity is not achieved if lower MELD patients have access only to NI donors at LM centers and little chance of transplantation at HM centers.

Allocation policy change was not the only variable impacting center behavior within the timeframe of our study. Creation of the NLRB²⁸ led to a decrease in MELD exception cases at both HM and LM centers. Only LM centers experienced a significant drop in HCC cases. If MMA_T remains disparate nationally, it will be important to

monitor access to transplant for patients with HCC at LM and HM centers. Similarly, we suspected that the pandemic may have altered transplant volume; however, our data suggest no differential impact on HM and LM centers. Lastly, we note a sharp uptick in transplantation for alcohol-associated liver disease at most centers. It is unclear whether this reflects true change in the incidence of ALD or a behavioral response to allocation change.

To better understand dynamics at the center level, we have used change in transplant volume and change in MMaT to categorize centers as Type I, II, or III. Type I centers have benefitted from allocation change and leveraged increasing volume to decrease MMaT. Assuming listing practices have not changed, one hopes this reflects earlier transplantation of sick patients and reduced mortality. Type II centers have shown great versatility. Most are LM centers that have seen a decrease in available I and S donor allografts, and volume has grown through increased utilization of NI and DCD grafts. Type III centers appear to have not adapted to allocation change or perhaps have other ongoing programmatic challenges that have led to decreased utilization of all donors. Allocation policy should be crafted to create a tide that helps “all ships rise.” It will be important to follow transplant volumes at Type III centers moving forward. Although classification cannot be absolute in a system this complex, we note that Type I centers are predominantly HM centers whereas Type II and III centers are predominantly LM centers.

Ongoing monitoring will continue to promote equity as allocation policy and transplant practice continue to co-evolve. The OPTN/UNOS identify transplant rate, post-transplant mortality, transportation time, and percentage of organs flown as critical metrics for monitoring in addition to variance in MMaT. Concerns about travel safety and cost^{8,15,29} have already arisen and are being reported.³⁰ We suggest the importance of looking within transplant volume to critically appraise donor usage. Unless best practices for aggressive donor utilization are identified and shared throughout the transplant community patient-level disparities will persist.

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DISCLOSURE

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

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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