The Effect of Acuity Circles on Deceased Donor Transplant and Offer Rates Across Model for End-Stage Liver Disease Scores and Exception Statuses

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Acuity circles (AC), the new liver allocation system, was implemented on February 4, 2020. Difference-in-differences analyses estimated the effect of AC on adjusted deceased donor transplant and offer rates across Pediatric End-Stage Liver Disease (PELD) and Model for End-Stage Liver Disease (MELD) categories and types of exception statuses. The offer rates were the number of first offers, top 5 offers, and top 10 offers on the match run per person-year. Each analysis adjusted for candidate characteristics and only used active candidate time on the waiting list. The before-AC period was February 4, 2019, to February 3, 2020, and the after-AC period was February 4, 2020, to February 3, 2021. Candidates with PELD/MELD scores 29 to 32 and PELD/MELD scores 33 to 36 had higher transplant rates than candidates with PELD/MELD scores 15 to 28 after AC compared with before AC (transplant rate ratios: PELD/MELD scores 29-32, $_{2.34}3.32_{4.71}$; PELD/MELD scores 33-36, $_{1.70}2.51_{3.71}$). Candidates with PELD/MELD scores 29 or higher had higher offer rates than candidates with PELD/MELD scores 15 to 28, and candidates with PELD/MELD scores 29 to 32 had the largest difference (offer rate ratios [ORR]: first offers, $_{2.77}3.95_{5.63}$; top 5 offers, $_{3.90}4.39_{4.95}$; top 10 offers, $_{4.85}5.30_{5.80}$). Candidates with exceptions had lower offer rates than candidates without exceptions for offers in the top 5 (ORR: hepatocellular carcinoma [HCC], $_{0.68}0.77_{0.88}$; non-HCC, $_{0.73}0.81_{0.89}$) and top 10 (ORR: HCC, $_{0.59}0.65_{0.71}$; non-HCC, $_{0.69}0.75_{0.81}$). Recipients with PELD/MELD scores 15 to 28 and an HCC exception received a larger proportion of donation after circulatory death (DCD) donors after AC than before AC, although the differences in the liver donor risk index were comparatively small. Thus, candidates with PELD/MELD scores 29 to 34 and no exceptions had better access to transplant after AC, and donor quality did not notably change beyond the proportion of DCD donors.

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Abbreviations: AC, acuity circles; CIT, cold ischemia time; DBD, donation after brain death; DCD, donation after circulatory death; DID, difference-in-differences; DSA, donation service area; HCC, hepatocellular carcinoma; LDRI, liver donor risk index; MELD, Model for End-Stage Liver Disease; MMaT, median MELD at transplant; MRR, median rate ratio; NLRB, National Liver Review Board; NM, nautical miles;

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Acuity circles (AC), or the new liver allocation policy, was implemented on February 4, 2020, and was designed to reduce the variation in median Model for End-Stage Liver Disease (MELD) score (ie, the measure of disease severity) at transplant across the United States. To achieve this goal, AC implemented the following 2 significant changes to the allocation of deceased donor livers:

1. AC uses concentric circles around the donor hospital for determining appropriate candidates for allocation. The previous allocation system used donation service areas (DSAs) and Organ Procurement and Transplantation Network (OPTN) regions, geographic entities originally created for administrative rather than allocation purposes.[1]
2. AC allocates to candidates in relatively narrow bands of disease severity: status 1A and 1B, Pediatric End-Stage Liver Disease (PELD) or MELD scores ≥37, PELD/MELD scores 33 to 36, PELD/MELD scores 29 to 32, PELD/MELD scores 15 to 28, and PELD/MELD scores <15. In contrast, the previous system used coarser bands of disease severity: status 1A and 1B, PELD/MELD scores ≥35, PELD/MELD scores 15 to 34, and PELD/MELD scores <15.

OPTN, Organ Procurement and Transplantation Network; ORR, offer rate ratio; PELD, Pediatric End-Stage Liver Disease; SRTR, Scientific Registry of Transplant Recipients; TRR, transplant rate ratio.

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For most donation after brain death (DBD) donors, AC prioritizes candidates within a band of disease severity through increasingly large concentric circles. That is, AC first offers the organ to candidates in the disease severity band and within 150 nautical miles (NM) of the donor hospital. If the organ was not accepted, AC then offers candidates in the disease severity band and between 150 and 250 NM from the donor hospital. Again, if the organ was not accepted, AC offers candidates in the disease severity band and between 250 and 500 NM from the donor hospital. If the organ was still not accepted, AC restarts the process for candidates in the next disease severity band. In contrast, for donation after circulatory death (DCD) donors, AC offers most candidates within the narrow concentric circle before offering to candidates in larger concentric circles (ie, AC places a greater emphasis on proximity for DCD than DBD donors).

These changes in allocation have several potential effects on liver candidates and recipients. The transition to concentric circles was intended to lower the variance of the median MELD at transplant (MMaT) across DSAs because of the broader distribution than in the previous allocation system. The second change may give candidates with MELD scores 29 to 34 better access to liver transplantation because of the more granular bands for allocating across disease severity. Importantly, a potential consequence of better access for candidates with PELD/MELD scores 29 to 34 is lower donor quality for recipients with PELD/MELD scores 15 to 28 (eg, higher liver donor risk index [LDRI] or a larger proportion of DCD donors).

In this article, we investigated the effect of AC on access to transplant for candidates across PELD/MELD categories and exception statuses (eg, hepatocellular carcinoma [HCC] versus non-HCC exceptions). Better access to liver transplantation, for example, for candidates with PELD/MELD scores 29 to 34 would indicate that AC better prioritized candidates by PELD/MELD scores than the previous allocation system. In addition, candidates with HCC and other exceptions make up a large proportion of the liver waiting list, and it is important to understand any changes in their access to transplant. Thus, difference-in-differences (DID) analyses separately estimated the effect of AC on deceased donor transplant rates and offer rates for patients across PELD/MELD categories and exception statuses. The median rate ratio (MRR) estimated geographic variability in deceased donor transplant and offer rates,[2] overall and across PELD/MELD categories and exception types. Lastly, transplant characteristics before and after

AC summarized differences in donor quality across different PELD/MELD categories and exception statuses.

Patients and Methods

This study used Scientific Registry of Transplant Recipient (SRTR) data. The SRTR data system includes data on all donors, candidates on the waiting list, and transplant recipients in the United States submitted by the members of the OPTN and has been described elsewhere.[3] The Health Resources and Services Administration, US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors.

FRAMEWORK FOR DID ANALYSES

The DID analyses estimated the change in deceased donor transplant and offer rates for PELD/MELD categories and the types of exceptions before and after AC compared with a reference level (candidates with PELD/MELD scores 15-28 and candidates without an exception, respectively). Specifically, the differences across PELD/MELD categories and types of exceptions before AC were estimated, and, separately, the differences across PELD/MELD categories and types of exceptions after AC were estimated. The effect of AC on, for example, candidates with PELD/MELD scores 29 to 32 was the difference in the differences between candidates with PELD/MELD scores 29 to 32 and PELD/MELD scores 15 to 28 after AC compared with before AC. Conceptually, the candidates with PELD/MELD scores 15 to 28 were the "control group," accounting for secular trends in deceased donor transplant and offer rates unrelated to the implementation of AC.

The candidate factors in the deceased donor transplant and offer rate models were age, allocation PELD/MELD, type of exception, sex, primary payer, and rural-urban commuting area classification of the candidate's zip code. In addition, models included an indicator for follow-up time after AC implementation (ie, February 4, 2020, to February 3, 2021), and the indicator had an interaction with each candidate factor. The interactions estimated the DID effects across allocation PELD/MELD categories and exception types.

MEDIAN RATE RATIO

The MRR estimated the geographic variability in deceased donor transplant and offer rates. The MRR is the median of the ratios for each combination of DSAs in which the larger rate ratio was divided by the smaller rate ratio.[2] In other words, the MRR is the median difference in transplant or offer rates when going from a DSA with a lower rate to a DSA with a larger rate. Larger MRRs suggest more inequity across DSAs in deceased donor transplant or offer rates.

MRRs were estimated for all candidates (ie, an overall MRR) and across PELD/MELD categories and exception types. Generalized linear mixed models with separate DSA-level random intercepts for the pre-AC and post-AC periods estimated the MRR before and after implementation of AC, respectively. For the overall MRR, the generalized linear mixed model included the linear predictors from the DID analyses as an offset, accounting for differences across candidate characteristics. For the MRR of PELD/MELD and exception type subgroups, the generalized linear mixed models only used candidates with the given characteristic of interest. For example, the MRRs before and after AC for PELD/MELD scores 29 to 32 only used active candidates with allocation PELD/MELD scores 29 to 32.

DECEASED DONOR TRANSPLANT RATE ANALYSES

Registrations on the liver waiting list between February 4, 2019, and February 3, 2021, were included in the cohort. Specifically, registrations were included if (1) the listing date was on or before February 3, 2021, and (2) the removal date was on or after February 4, 2019. Candidates were followed until (1) deceased donor transplant, (2) removal from the waiting list for reasons other than deceased donor transplant, or (3) end of the cohort period, whichever was first, and the model censored for removal from the waiting list for reasons other than deceased donor transplant and the end of the cohort period. The underlying model was a piecewise exponential model with the timescale set to calendar time. The baseline hazard included an effect for each month before and after implementation of AC, adjusting for temporal trends in deceased donor transplant rates. Inactive time was not included in the analysis.

OFFER RATE ANALYSES

The offer rate analyses included liver match runs submitted between February 4, 2019, and February 3, 2021. Only match runs with at least 1 acceptance were included, and offers after the last acceptance on a match run were removed. A Poisson model estimated the rate of offers for registrations during a status update or the period of time spent at a particular allocation PELD/MELD or status 1A/1B. The outcomes of interest were the number of offers a candidate received per person-year in (1) the first offer of a match run, (2) the top 5 offers of a match run, and (3) the top 10 offers of a match run. The following 3 models were estimated for each outcome: (1) a model with all offers (ie, an overall analysis), (2) a model with offers from DBD donors, and (3) a model with offers from DCD donors. Each model used an offset equal to the natural log of days in the status and included an overdispersion term, allowing a more flexible mean-variance relationship than a typical Poisson model. Similar to the model for deceased donor transplant rates, the offer rate model adjusted for monthly effects before and after implementation of AC.

TRANSPLANT CHARACTERISTICS

Liver transplants performed between February 4, 2019, and February 3, 2021 were included. Means and standard deviations summarized the differences in transplant characteristics across PELD/MELD and exception categories before and after AC. The LDRI calculation only included factors known at allocation (ie, partial/split status, regional/national share status, and CIT were not included).[4] Street addresses calculated the straight-line distance between the donor and recipient hospitals.

SENSITIVITY ANALYSES: COVID-19 AND THE NATIONAL LIVER REVIEW BOARD

The implementation of AC overlapped significantly with the emergence of COVID-19 and the implementation of the National Liver Review Board (NLRB). Two sensitivity analyses assessed the potential influence of these events. Specifically, the COVID-19 sensitivity analyses restricted the post-AC period to February 4, 2020 to March 12, 2020, the day before the declaration of national emergency. The point estimates of the DID analyses were compared to the primary analyses. The confidence intervals were not emphasized because of less follow-up and correspondingly wider intervals. The NLRB sensitivity analyses restricted follow-up to after the implementation of the NLRB (May 14, 2019), and the post-AC follow-up ended on November 24, 2020, ensuring the same number of days in the pre-AC and post-AC periods. The NLRB sensitivity analyses focused on the DID effects and MRRs across exception types because NLRB changed the implementation of exceptions.

Point estimates and confidence intervals were presented as $_{a}b_{c}$, where b was the point estimate and *a* and *c* were the lower and upper limits of the 95% confidence interval, respectively. *P* values and statements of statistical significance were not included in part because of the American Statistical Association statement that *P* values in isolation should not be used for interpreting effects.[5] All analyses were performed in R version 3.5.2, and the "dplyr" package was used for data management and cleaning.[6,7]

Results

DECEASED DONOR TRANSPLANT RATES

The characteristics of the first status were similar before and after implementation of AC (Table 1). Most registrations were patients aged 50 to 64 years at listing and had PELD/MELD scores of less than 15 or 15 to 28. The majority of registrations did not have an exception during their first status (88% and 89% before and after implementation of AC, respectively). Lastly, most registrations had non–public health insurance providers (~50%) and lived in metropolitan zip codes (85%).

Table 2 presents the DID results for deceased donor transplant rates. Transplant rates were substantially higher for candidates with PELD/MELD scores 29 to 32 and 33 to 36 than for candidates with PELD/MELD scores 15 to 28 after implementation of AC compared with before (transplant rate ratio [TRR]: PELD/MELD 29-32, $_{2.34}3.32_{4.71}$; 33-36, $_{1.70}2.51_{3.71}$). In contrast, candidates with PELD/MELD scores less than 15 and 37 or higher had less dramatic differences than candidates with PELD/MELD scores 15 to 28 (TRR: PELD/MELD less than 15, $_{0.75}1.33_{2.36}$; 37 or higher, $_{1.00}1.40_{1.95}$). Transplant rates were lower for candidates with HCC and other exceptions than candidates without exceptions after implementation of AC compared with before AC (TRR: HCC exceptions, $_{0.56}0.80_{1.14}$; other exceptions, $_{0.41}0.65_{1.03}$).

The overall MRR decreased from 1.79 before AC to 1.63 after AC (Table 3), suggesting slightly lower

TABLE 1. Descriptive Statistics for Registrations on the Waiting List During the Year Before Implementation of AC and the Year After Implementation of AC

Characteristic	Before AC	After AC
Number of registrations	26,957	25,860
Age at listing		
Younger than 18 years	1181 (4)	1077 (4)
18-34 years	1689 (6)	1701 (7)
35-49 years	4904 (18)	4942 (19)
50-64 years	13,799 (51)	12,785 (49)
65 years and older	5384 (20)	5355 (21)
Current PELD/MELD		
Inactive	3431 (13)	3436 (13)
PELD/MELD: less than 15	10,092 (37)	9426 (36)
PELD/MELD: 15-28	9830 (36)	9362 (36)
PELD/MELD: 29-32	1317 (5)	1247 (5)
PELD/MELD: 33-36	831 (3)	804 (3)
PELD/MELD: 37 or higher	974 (4)	1147 (4)
Status 1B	88 (0)	73 (0)
Status 1A	394 (1)	365 (1)
Type of exception		
No exception	23,593 (88)	23,016 (89)
Exception: HCC	2234 (8)	2209 (9)
Exception: other	1130 (4)	635 (2)
Sex		
Female	10,461 (39)	10,069 (39)
Male	16,496 (61)	15,791 (61)
Candidate primary payer		
Missing	6 (0)	130 (1)
Nonpublic insurance	13,942 (52)	13,266 (51)
Public insurance: Medicare and others	7821 (29)	7371 (29)
Public insurance: Medicaid	5188 (19)	5093 (20)
Candidate rural-urban commuting area classification		
Missing	246 (1)	221 (1)
Rural	719 (3)	666 (3)
Small town	1015 (4)	988 (4)
Micropolitan	2180 (8)	2121 (8)
Metropolitan	22,797 (85)	21,864 (85)

NOTE: Data are provided as n and n (%). Registrations were included, as appropriate, in the before and after AC periods. Only the first status of a registration was included before and after AC.

overall variability in deceased donor transplant rates across DSAs. The MRRs for candidates with PELD/MELD scores between 15 and 32 and status 1A were lower after AC than before AC. MRRs were also lower for candidates without an exception or other exceptions after AC than before AC. In contrast, MRRs were higher for candidates with PELD/MELD scores less than 15, 33 or higher, and candidates with HCC after AC than before AC. Thus, the overall MRR was lower after AC, but some candidate subgroups had lower MRRs and other subgroups had higher MRRs.

TABLE 2. The DID in Adjusted TRRs Before and After the Implementation of AC

Candidate Characteristic	Level	TRR
PELD/MELD	Less than 15	$_{0.75}1.33_{2.36}$
	15-28	Reference
	29-32	$_{2.34}3.32_{4.71}$
	33-36	$_{1.70}2.51_{3.71}$
	37 or higher	$_{1.00}1.40_{1.95}$
	Status 1B	$_{0.29}0.93_{3.00}$
	Status 1A	$_{0.65}1.29_{2.57}$
Type of exception	None	Reference
	HCC	$_{0.56}0.80_{1.14}$
	Other	$_{0.41}0.65_{1.03}$

NOTE: For example, the deceased donor transplant rates for candidates with PELD/MELD scores 29 to 32 were 232% higher than candidates with PELD/MELD scores 15 to 28 after implementation of AC compared with before implementation (95% confidence interval, 134%-371%).

TABLE 3. The MRRs for Deceased Donor Transplant Rates Before and After Implementation of AC

Candidate Characteristic	Level	Before AC	After AC
Overall		1.79	1.63
PELD/MELD	Less than 15	2.44	2.50
	15-28	2.32	2.04
	29-32	2.21	1.97
	33-36	1.72	2.00
	37 or higher	1.87	1.92
	Status 1B	–	–
	Status 1A	1.61	1.34
Type of exception	None	1.85	1.70
	HCC	1.40	1.53
	Other	1.69	1.48

OFFER RATES

The distribution of characteristics for first offers, top 5 offers, and top 10 offers had notable differences before and after implementation of AC (Table 4). For example, candidates with PELD/MELD scores 15 to 28 received a notably smaller proportion of offers after AC than before AC (ie, 4% lower for first offers, 9% lower for top 5 offers, and 10% lower for top 10 offers), whereas candidates with PELD/MELD scores 37 or

TABLE 4. Descriptive Statistics Across Different Characteristics for the First Offers, Top 5 Offers, and Top 10 Offers on a Match Run

	First Offers		Top 5 Offers		Top 10 Offers	
Candidate Characteristic	Before AC	After AC	Before AC	After AC	Before AC	After AC
Age at listing						
Younger than 18 years	2179 (26)	2002 (24)	7238 (23)	7876 (22)	10032 (21)	11855 (20)
18-34 years	964 (11)	1003 (12)	2920 (9)	3335 (9)	4213 (9)	5270 (9)
35-49 years	1553 (18)	1868 (22)	5549 (17)	7777 (22)	7988 (16)	12366 (21)
50-64 years	2806 (33)	2529 (30)	12042 (38)	11631 (33)	19235 (39)	20625 (35)
65 years and older	908 (11)	1001 (12)	4258 (13)	4854 (14)	7324 (15)	8649 (15)
Current PELD/MELD						
Inactive	105 (1)	133 (2)	262 (1)	442 (1)	314 (1)	633 (1)
PELD/MELD: less than 15	29 (0)	32 (0)	302 (1)	273 (1)	579 (1)	618 (1)
PELD/MELD: 15-28	844 (10)	544 (6)	7552 (24)	5380 (15)	15762 (32)	12845 (22)
PELD/MELD: 29-32	582 (7)	523 (6)	4157 (13)	4557 (13)	7627 (16)	10284 (18)
PELD/MELD: 33-36	905 (11)	651 (8)	5270 (16)	5136 (14)	7369 (15)	9659 (16)
PELD/MELD: 37 or higher	3419 (41)	3294 (39)	10102 (32)	13253 (37)	12074 (25)	17533 (30)
Status 1B	1032 (12)	977 (12)	2608 (8)	3399 (10)	3300 (7)	4101 (7)
Status 1A	1494 (18)	2249 (27)	1754 (5)	3033 (9)	1767 (4)	3092 (5)
Type of exception						
No exception	6281 (75)	7048 (84)	21303 (67)	26904 (76)	30302 (62)	41849 (71)
Exception: HCC	366 (4)	246 (3)	2919 (9)	2267 (6)	6231 (13)	5427 (9)
Exception: other	1763 (21)	1109 (13)	7785 (24)	6302 (18)	12259 (25)	11489 (20)
Sex						
Female	4294 (51)	4229 (50)	15354 (48)	17323 (49)	22382 (46)	28137 (48)
Male	4116 (49)	4174 (50)	16653 (52)	18150 (51)	26410 (54)	30628 (52)
Candidate primary payer						
Missing	1 (0)	79 (1)	4 (0)	247 (1)	5 (0)	327 (1)
Nonpublic insurance	4156 (49)	4276 (51)	15613 (49)	18049 (51)	23595 (48)	29572 (50)
Public insurance: Medicare and others	1933 (23)	1571 (19)	8224 (26)	7709 (22)	13357 (27)	13963 (24)
Public insurance: Medicaid	2320 (28)	2477 (29)	8166 (26)	9468 (27)	11835 (24)	14903 (25)
Candidate rural-urban commuting area classification						
Missing	75 (1)	100 (1)	378 (1)	315 (1)	580 (1)	543 (1)
Rural	267 (3)	272 (3)	1140 (4)	1063 (3)	1557 (3)	1625 (3)
Small town	289 (3)	437 (5)	1348 (4)	1604 (5)	2116 (4)	2402 (4)
Micropolitan	712 (8)	640 (8)	2893 (9)	2940 (8)	4631 (9)	5366 (9)
Metropolitan	7067 (84)	6954 (83)	26248 (82)	29551 (83)	39908 (82)	48829 (83)

NOTE: Data are provided as n (%). Inactive registrations had offers because inactive time was measured to the day, and offers were sometimes made before inactivation on a given day.

higher and status 1A received larger proportions of top offers after AC than before AC. Candidates with exceptions received a smaller proportion of offers after AC than before AC. In addition, some PELD/MELD and exception groups received a larger proportion of top 10 offers than first offers. For example, candidates with PELD/MELD scores 15 to 28 received 6% of first offers but 22% of top 10 offers after AC. Similarly, candidates with HCC exceptions received 3% of first offers but 9% of top 10 offers after AC.

Offer rates were substantially higher for candidates with PELD/MELD scores 29 and higher or status 1A/1B compared with candidates with PELD/MELD scores 15 to 28 after implementation of AC compared with before AC (Fig. 1). Candidates with PELD/MELD scores 29 to 32 had the largest relative

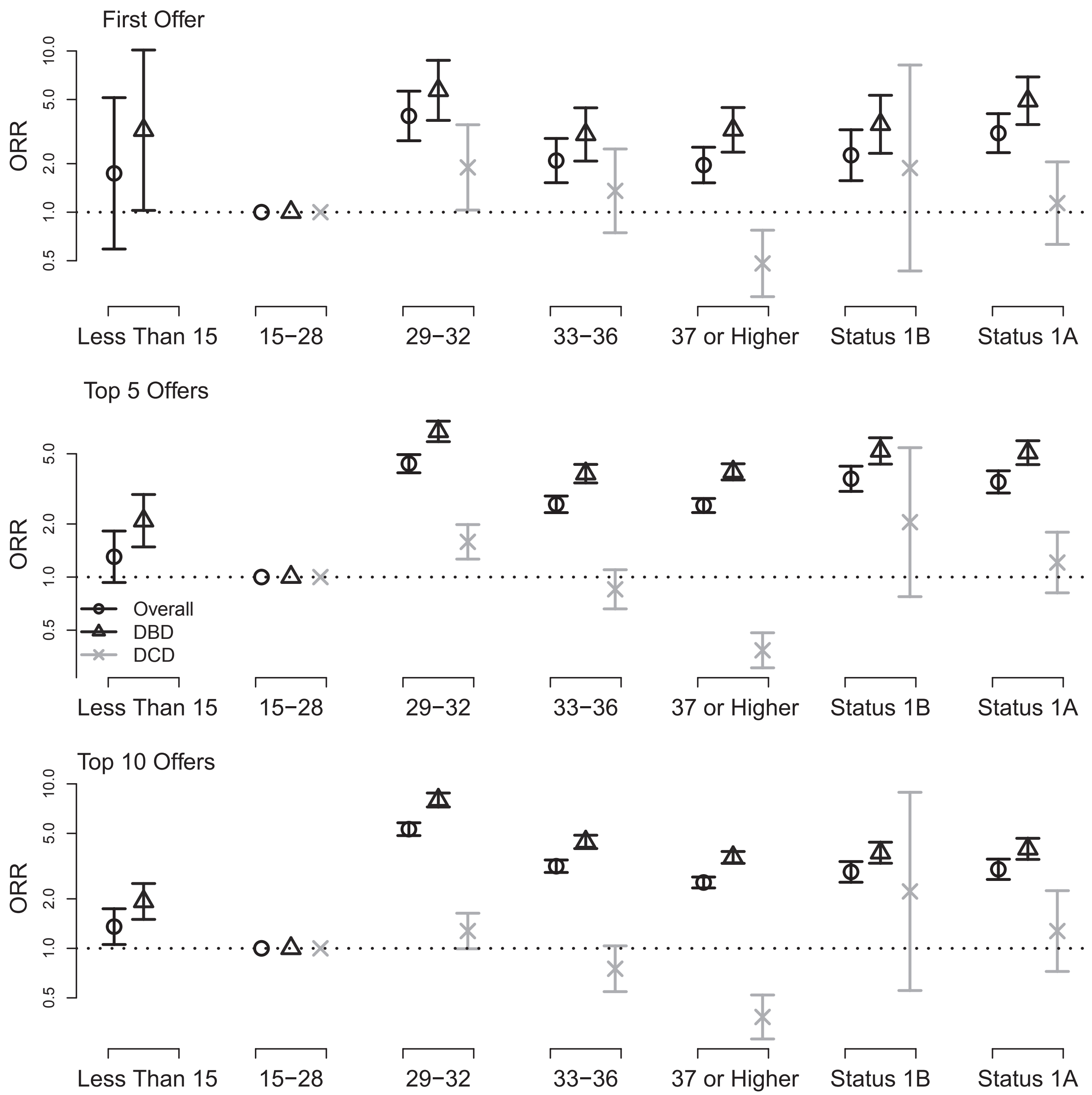

FIG. 1. The DID analyses of offer rates across PELD/MELD categories for first offers (top panel), top 5 offers (middle panel), and top 10 offers (bottom panel).

increase in offer rates compared with candidates with PELD/MELD scores 15 to 28. In addition, the differences with candidates with PELD/MELD scores 15 to 28 were larger for the rates of top 5 and 10 offers of a match run than the differences for the rate of first offers on a match run. Lastly, the offer rates for DCD donors had a dramatically different pattern: candidates with PELD/MELD scores 29 to 32 had slightly higher offer rates for DCD donors after AC than before AC, whereas candidates with PELD/MELD scores 37 or higher had lower offer rates for DCD donors.

After adjusting for the effect of allocation PELD/MELD and other candidate characteristics, Fig. 2 illustrates that overall offer rates for the first offer on the

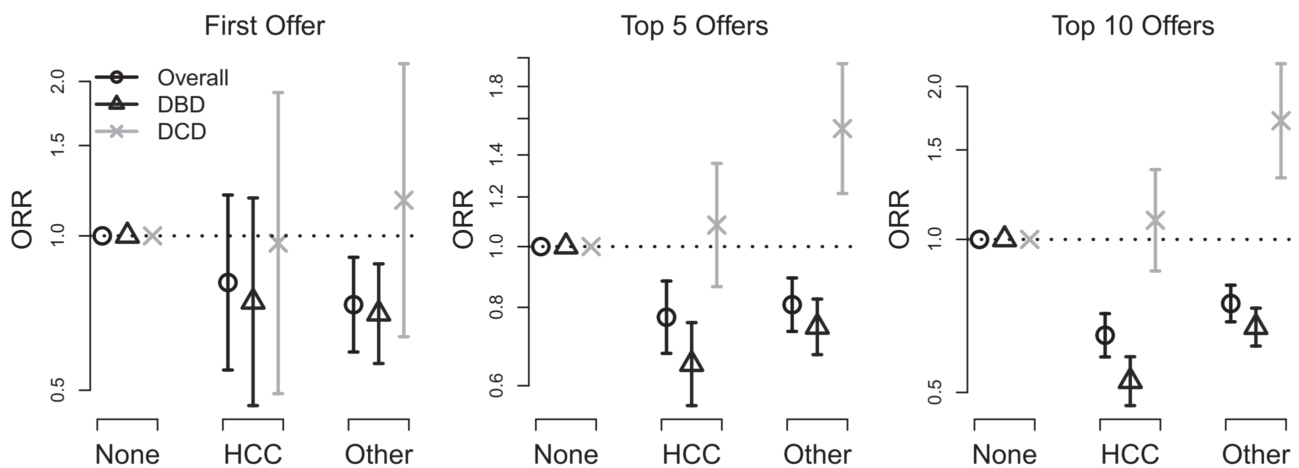

FIG. 2. The DID analyses of offer rates across exception types for first offers (left panel), top 5 offers (middle panel), and top 10 offers (bottom panel).

TABLE 5. The MRRs for Offer Rates Before and After Implementation of AC

		First Offers		Top 5 Offers		Top 10 Offers	
Candidate Characteristic	Level	Before AC	After AC	Before AC	After AC	Before AC	After AC
Overall		1.84	1.56	1.76	1.52	1.71	1.52
PELD/MELD	Less than 15	–	–	5.87	4.29	6.15	4.03
	15-28	2.70	3.08	2.89	2.42	2.66	2.22
	29-32	3.37	2.49	2.42	1.99	2.06	1.90
	33-36	2.30	2.01	1.74	1.66	1.58	1.73
	37 or higher	2.05	1.81	1.80	1.89	1.76	1.91
	Status 1B	2.50	3.06	2.25	3.06	2.26	3.13
	Status 1A	1.79	1.77	1.71	1.76	1.71	1.75
Type of exception	None	1.80	1.96	1.84	1.77	1.86	1.73
	HCC	1.79	2.54	1.64	2.03	1.58	1.76
	Other	2.85	2.96	2.12	2.66	1.85	2.50

match run were lower for candidates with HCC exceptions compared with candidates without exceptions after implementation of AC than before AC (offer rate ratio [ORR]: ${}_{0.55}0.81_{1.20}$), although HCC exceptions had progressively lower overall offer rates for the top 5 and 10 offers on the match run compared with candidates without exceptions after implementation of AC compared with before AC (ORR: top 5 offers, ${}_{0.68}0.77_{0.88}$; top 10 offers, ${}_{0.59}0.65_{0.71}$). In contrast, candidates with other exceptions had consistently lower overall offer rates for the top 1, 5, and 10 offers on the match run after implementation of AC compared with before AC (ORR: top 1 offers, ${}_{0.59}0.73_{0.91}$; top 5 offers, ${}_{0.73}0.81_{0.89}$; top 10 offers, ${}_{0.69}0.75_{0.81}$). Offer rates for DCD donors in the top 5 and 10 offers on the match run had a dramatically different pattern: candidates with HCC had a slightly higher rate of DCD offers (ORR: top 5 offers, ${}_{0.86}1.08_{1.36}$; top 10 offers, ${}_{0.87}1.09_{1.37}$), whereas candidates with other exceptions had a notable increase in the DCD offer rate (ORR: top 5 offers, ${}_{1.22}1.54_{1.96}$; top 10 offers, ${}_{1.32}1.71_{2.22}$). Thus, candidates with exceptions generally had lower offer rates for DBD donors but similar or higher rates for DCD donors.

The overall MRRs were lower after AC than before AC for overall offer rates of the top 1, 5, and 10 offers on the match run (Table 5), suggesting lower variability in offer rates across DSAs. Only candidates with PELD/MELD scores 29 to 32 or HCC exceptions had consistent differences in MRRs after AC than before AC. MRRs were consistently lower for candidates with PELD/MELD scores 29 to 32, suggesting better equity in access to liver transplant after AC. In contrast, MRRs were consistently higher for candidates with HCC after AC than before AC, suggesting worse equity in access for such candidates. The MRRs for the other candidate subgroups did not consistently increase or decrease after AC compared with before AC.

CHARACTERISTICS OF TRANSPLANTS

Figure 3 presents the transplant characteristics across PELD/MELD categories. The LDRI was slightly higher after AC for recipients with PELD/MELD scores 15 to 28 and slightly lower for recipients with PELD/MELD scores 29 to 32. However, these differences were relatively small compared with the differences across PELD/MELD categories. Recipients with PELD/MELD scores 15 to 28 received a notably higher proportion of DCD donors after AC compared with before AC (before AC, 13%; after AC, 19%), whereas recipients with PELD/MELD scores 29 to 32 received a lower proportion of DCD donors (before AC, 8%; after AC, 3%). Lastly, the distance between donor and transplant hospitals was higher after AC across PELD/MELD categories. Yet, the cold ischemia time (CIT) was only slightly higher after AC.

Figure 4 presents the transplant characteristics across exception types. LDRI had, at best, small changes before and after AC within each exception category. Recipients with HCC exceptions had a notable increase in the proportion of DCD donors after AC (before AC, 12%; after AC, 16%). In contrast, recipients with other exceptions or no exceptions had a much smaller increase in the proportion of DCD donors. The average distance between the donor and transplant hospital increased across the different exception types. Recipients with other exceptions, in particular, had a relatively large increase in the distance between the donor and transplant hospital (~100 NM). However, the larger average distance only corresponded to approximately 30 additional minutes of average CIT.

Discussion

Candidates with PELD/MELD scores 29 to 32 consistently had the largest differences in deceased donor transplant and offer rates after compared with before implementation of AC, demonstrating substantially better access to liver transplant for such candidates. Notably, candidates with PELD/MELD scores 29 to 32 did not have regional sharing in the previous allocation system, which started at a PELD/MELD score of 35. The allocation of livers in more granular ranges of PELD/MELD (eg, 29-32 and 33-36 instead of the 15-34 range used in the previous allocation system) was a potential reason for the substantially improved access to transplant for candidates with PELD/MELD scores 29 to 32. Thus, because more granular ranges of PELD/MELD may better prioritize candidates by disease severity, splitting PELD/MELD scores 15 to 28 into several groups with more narrow ranges may improve access for candidates with higher PELD/MELD scores in the 15 to 28 range.

The larger proportion of DCD donors for candidates with PELD/MELD scores 15 to 28 and HCC exceptions aligned in part with the notable differences in offer rates for DCD donors compared with DBD donors, suggesting that the similar or better access to DCD donors partly offset the lower access to DBD donors. Of importance, candidates with PELD/MELD scores 15 to 28 and/or HCC exceptions could have worse posttransplant outcomes because of the higher proportion of DCD donors.[8] However, LDRI had less apparent differences, suggesting less risk of worse posttransplant outcomes. Regardless, further monitoring of the effect of AC on posttransplant outcomes for these patients is warranted.

Both AC and the previous liver allocation system have hard boundaries between candidates based on PELD/MELD and distance between the donor and recipient hospitals. For example, within each PELD/MELD band, candidates within 150 NMs of the donor hospital receive offers before candidates between 150 and 250 NMs of the donor hospital. Thus, a candidate with a PELD/MELD score of 29 and 200 NMs from the donor hospital has significantly different priority than a candidate with a PELD/MELD score of 28 and 200 NMs from the donor hospital despite only minor clinical differences. A continuous allocation system avoids these “cliffs” with gradual rather than sudden changes in priority over PELD/MELD scores and distance between donor and recipient hospitals.[9,10] Thus, the development of a continuous allocation system would help ensure a more equitable allocation system.

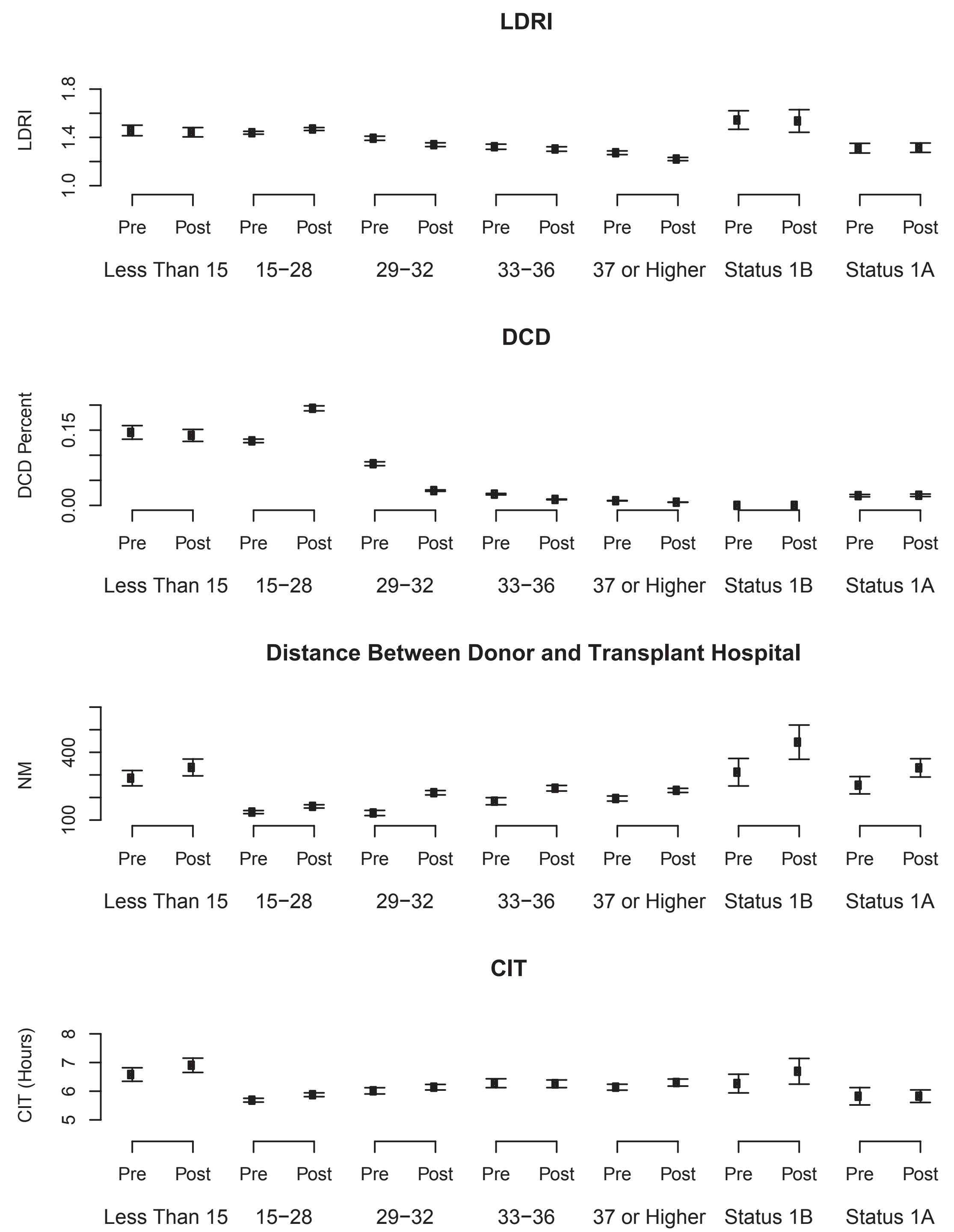

FIG. 3. The LDRI, DCD status, distance between donor and transplant hospital, and CIT before and after implementation of AC across PELD/MELD categories.

The distance between donor and recipient hospitals historically failed to explain most of the variation in CIT.[11] The relatively small increases in CIT despite the larger average distances between the donor and transplant hospitals further suggests that CIT has a complex set of determinants that extend beyond the

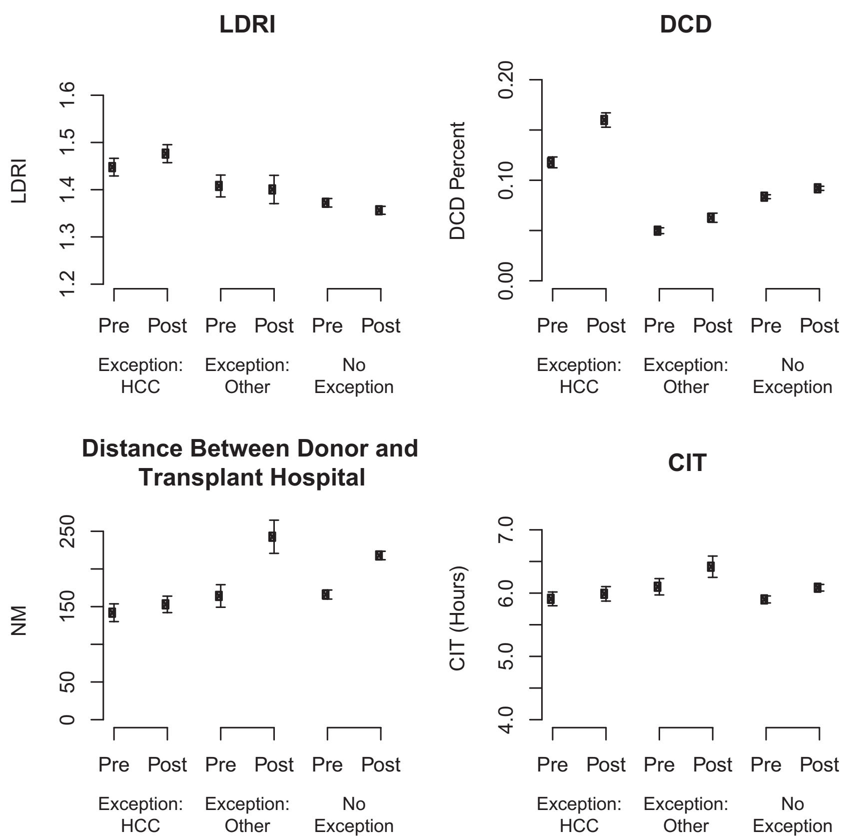

FIG. 4. The LDRI, DCD status, distance between donor and transplant hospital, and CIT before and after implementation of AC across types of exception categories.

distance between the donor and recipient hospital. A better understanding of these determinants and their relationship to broader sharing would help in the development of continuous allocation.

The implementation of the NLRB in May 2019 was designed to lower the relative priority of candidates with HCC and overlapped with the before AC period.[12] However, sensitivity analyses suggested similar differences for HCC and other exception candidates when only including post-NLRB follow-up (Supporting Tables 7 and 8). Importantly, although most candidates with HCC have allocation PELD/MELD scores 15 to 28, the overall lower allocation priority of candidates with PELD/MELD scores 15 to 28 likely does not explain these results because the analyses adjusted for allocation PELD/MELD. Regardless, candidates with exceptions had less access to transplant after implementation of AC compared with before AC, which was a specific goal of the NLRB.

Reaching a consensus on the appropriate priority for candidates with HCC and other exceptions has been challenging.[13] Exceptions exist because laboratory PELD/MELD values do not appropriately measure true disease severity for such diagnoses (eg, HCC). The handling of exceptions in liver allocation has evolved over time, usually trying to balance the acute disease of patients with high laboratory PELD/MELD scores with the need for timely transplant for groups such as candidates with HCC. Within AC allocation, the lower access to transplantation for candidates with HCC and other exceptions may align with the relative disease severity of the candidates with exceptions compared with candidates with no exceptions. However, AC and the NLRB were not designed to equalize the waitlist mortality rates between candidates with exceptions and no exceptions. Instead, candidates with exceptions historically had too much priority and therefore the NLRB gave candidates with exceptions less priority.[14] Thus, further research should focus on trying to place the disease severity of candidates with HCC and other exceptions onto the same scale as candidates with no exceptions (ie, a MELD-type score for candidates with HCC).[13,15,16] Such information could help ensure equitable access to liver transplant for candidates with exceptions and candidates with no exceptions.

A primary goal of AC was to reduce the variability in MMaT across DSAs, corresponding to a reduction in disparities in access to deceased donor liver transplants. Recent research suggested that AC achieved, at best, a minor reduction in the variability of MMaT across DSAs in the early days following implementation,[17-19] which aligns with the relatively small reduction in the overall MRRs for deceased donor transplant and offer rates. Yet the higher deceased donor transplant and offer rates for candidates with higher PELD/MELD scores are not well aligned with a small reduction in the variance of MMaT because higher transplant and offer rates should increase the proportion of high PELD/MELD transplants. There are at least 3 potential explanations for these contradictory results.

1. The proportion of candidates with PELD/MELD scores of 29 or higher was 13% of the waiting list (see Table 1) and approximately 50% of transplant recipients,[20] potentially too small to significantly impact MMaT across DSAs.
2. Offer acceptance practices have significant variation across transplant programs and are associated with MMaT across DSAs. AC could reduce the effect of donor supply and demand on MMaT, but not the effect of offer acceptance practices, an independent predictor of MMaT across DSAs.[21]
3. Programs are still calibrating to AC, and the initial year after implementation was not enough time to observe potential reductions in the variability of MMaT. This issue is particularly relevant because of the potential changes caused by the emergence of COVID-19.

A better understanding of why better prioritization across PELD/MELD scores may or may not lead to lower variability in MMaT across DSAs is critical for ensuring that future allocation policies achieve their stated goals. For example, a better understanding of the determinants could guide modifications to the liver simulation allocation model, allowing for a better-informed policy-making process.

Offer acceptance practices may have changed after the implementation of AC, potentially modifying the impact of higher offer rates. For example, candidates with PELD/MELD scores 29 or higher had higher offer rates after AC, but the differences in deceased donor transplant rates were comparatively small. Thus, offer acceptance rates were potentially lower for such candidates after implementation of AC. The effect of AC on offer acceptance practices deserves further investigation because offer acceptance rates are a surrogate of system efficiency and were lower for candidates with high PELD/MELD scores after the implementation of Share 35.[22]

The emergence of COVID-19 potentially confounded the evaluation of AC mostly because of overlapping time periods. However, if the emergence of COVID-19 had different effects across the levels of candidate PELD/MELD scores and type of exception, the AC effect would include the effect of both AC and COVID-19 (ie, the AC effect would be confounded). Sensitivity analyses showed similar effects with wider confidence intervals for the post-AC period prior to the declaration of a national emergency because of COVID-19 (February 4, 2020-March 12, 2020), suggesting a lower risk of confounding (Supporting Tables 1 and 2). However, it is fundamentally difficult to understand the effect of AC outside of COVID-19.

In conclusion, the implementation of AC improved access to liver transplantation for candidates with PELD/MELD scores 29 or higher, especially for candidates with PELD/MELD scores 29 to 32. These candidates did not have regional sharing under the previous allocation system, suggesting that narrower bands of PELD/MELD scores can improve prioritization of liver candidates by disease severity.

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