Published in final edited form as:

Liver Transpl. 2017 May ; 23(5): 604–613. doi:10.1002/lt.24749.

Share 35 Changes Center Level Liver Acceptance Practices

David S. Goldberg, MD, MSCE^{1,2,3}, Matthew Levine, MD, PhD⁴, Seth Karp, MD⁵, Richard Gilroy⁶, and L Peter, Abt, MD⁴

¹Division of Gastroenterology, Department of Medicine, University of Pennsylvania

²Center for Clinical Epidemiology and Biostatistics, Perelman School of Medicine at the University of Pennsylvania

³Leonard Davis Institute of Health Economics, University of Pennsylvania

⁴Division of Transplantation, Department of Surgery, Hospital of the University of Pennsylvania, Philadelphia, PA, USA

⁵Department of Surgery, Vanderbilt University Medical Center, Nashville, TN

⁶Division of Gastroenterology, Department of Medicine, Intermountain Medical Center, Murray, UT

Abstract

Share 35 was implemented to provide improved access to organs for patients with MELD scores 35. However, little is known about the impact of Share 35 on organ offer acceptance rates. We evaluated all liver offers to adult patients that were ultimately transplanted between 1/1/2011–12/31/2015. The analyses focused on patients ranked in the top five positions of a given match run, and used multi-level mixed-effects models, clustering on individual waitlist candidate and transplant center. There was a significant interaction between Share 35 era and MELD category ($p < 0.001$). Comparing offers to MELD score 35 patients, offers post-Share 35 were 36% less likely to be accepted compared to offers to MELD score 35 patients pre-Share 35 (adjusted OR: 0.64). There was no clinically meaningful difference in the DRI of livers that were declined for patients with an allocation MELD score 35 in the pre- vs post-Share 35 era. Organ offer acceptance rates for patients with an allocation MELD 35 decreased in every region post-Share 35; the magnitude of these changes was bigger in regions 2, 3, 4, 5, 6, 7, and 11, compared to regions 8 and 9 that had regional sharing in place pre-Share 35. There were significant changes in

Corresponding Author: David Goldberg, MD, MSCE, Blockley Hall, 423 Guardian Drive, Room 730, Philadelphia, PA 19104, Phone: 215-746-8598, Fax: 215-349-5915, david.goldberg@uphs.upenn.edu.

Conflicts of Interest: The authors of this manuscript have no conflicts of interest to disclose as it pertains to this manuscript.

Disclosures

None of the authors have any potential conflicts of interest as it pertains to this manuscript. The study protocol and final version was approved by HRSA.

We list the relevant grant information below:

1. This work was supported in part by Health Resources and Services Administration contract 234-2005-37011C. The content is the responsibility of the authors alone and does not necessarily reflect the views or policies of the Department of Health and Human Services, the Center for Medicare and Medicaid Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.
2. David Goldberg: K08 DK098272

organ offer acceptance rates at the center level pre- vs post-Share 35, and these changes varied across centers ($p < 0.001$).

Conclusions—In liver transplant candidates achieving a MELD score ≥ 35 , liver acceptance of offers declined significantly after implementation of Share 35. The alterations in behavior at the center level suggest that practice patterns changed as a direct result of Share 35. Changes in organ acceptance under even broader organ sharing (redistricting) would likely be even greater, posing major logistical and operational challenges, while potentially increasing discard rates, thus decreasing the total number of transplant nationally.

Keywords

organ offer; decline; waitlist mortality

INTRODUCTION

Between 2002 and 2013, prioritization on the liver transplant (LT) waitlist for patients with chronic liver failure (CLF; excludes Status 1 patients with acute liver failure) followed a sickest-first prioritization whereby organs were first distributed at the local level of the donor service area (DSA). However, on June 18, 2013, Share 35 was enacted to allow for broader sharing of organs within Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) regions for patients with Model for End-Stage Liver Disease (MELD) scores ≥ 35 . This policy was enacted because of the high waitlist mortality in patients with the highest MELD scores, and sought to decrease waitlist mortality by expanding the donor pool for these patients.^{1,2}

As a consequence of Share 35, patients with MELD scores ≥ 35 have had an increased number of organ offers, the intention of broader regional sharing.^{3,4} An early evaluation of organ offer and match run data in the first year after Share 35 demonstrated that organ offer acceptance rates for the highest MELD patients decreased.³ This was an important finding, however several questions remain unanswered: 1) Was the change in acceptance rates a temporary change or did it represent a sustained behavioral change?; 2) How did practice patterns change pre- vs post-Share 35 for those with a MELD < 35 (interaction of MELD score and era); and 3) Were there observed among-center differences in organ offer acceptance rates?

An understanding of the changes in behavior after implementation of this policy is more than just an academic exercise. In liver transplantation, we rely on the Liver Simulation Allocation Models (LSAM) to predict the impact of policy changes, and based upon these calculations, make decisions to enact policies. LSAM acceptance rates are based on existing behaviors, and LSAM cannot predict how changes in behavior may impact predictions, and specifically, “LSAM assumes that all centers and OPOs implement allocation policies in the same way and exhibit the same organ acceptance behavior. LSAM also does not model any directed or expedited allocation of donated organs.”⁵ For these reasons, evaluating how center behavior changes with respect to organ acceptance is critical if we choose to accurately predict the full impact of future policies associated with broader organ sharing.

METHODS

Study sample

We evaluated data from the OPTN/UNOS to evaluate all organ offers (match runs) to adult patients between January 1, 2011 through December 31, 2015. This allowed for an analysis of approximately 2.5 years of pre- and post-Share 35. These organ offer data only included data on livers that were ultimately transplanted. We focused analyses on patients ranked in the top five positions of a given match run (if applicable) as nearly three-quarters of all organ transplants occur in these patients (this included status 1 patients and offers that were offered regionally and then locally and vice versa). Furthermore, the highest-ranked patients are those whose rank on a given match run would be most influenced by the Share 35 policy.⁶

Out of the total 31,666 unique match runs during the study period where the liver was transplanted, we excluded match runs in which the highest-ranked patient was <18 years of age (n=7,929 match runs) or a multi-organ transplant candidate (excluding simultaneous liver-kidney; n=904 match runs) because the decision to accept or decline these offers is influenced by factors outside the scope of this analysis. We also excluded directed-donation organ offers (n=317 match runs) or offers for which critical donor data (e.g., age) were missing (n=14 match runs).

Covariates

Recipient covariates included: age, sex, allocation MELD score (the higher value of the calculated or exception MELD score), race/ethnicity⁷, previous liver transplantation, and receipt of hepatocellular carcinoma (HCC) or other exception points (which increase a patient's priority beyond their calculated MELD score⁷). Donor covariates included: sex, height, weight, age, race/ethnicity, cause of death, donation after cardiac death status, rank position on match run, and share type. Share type refers to the geographic location of the donor with regards to the patient offered the organ. Local transplant-center density was modeled as the number of liver transplant centers within a donor service area. All of these factors have previously been shown to be associated with acceptance of organ offers.⁶ Lastly, we evaluated the interaction of era (pre- vs post-Share 35) and MELD category of match run (<35, 35, and Status 1). We included patients from Region 8 and 9, as these regions already had broader regional sharing in place prior to Share 35 (both before 2007), and status 1 patients. This inclusion allowed us to determine if observed changes in acceptance rates were likely related to the Share 35 policy, or temporal changes in acceptance patterns independent of Share 35. Thus, Status 1 patients and patients from regions 8 and 9 served as controls for a pseudo difference-in-differences approach for regional analyses and MELD status comparisons as changes in acceptance rates for these patients would be more likely to reflect temporal changes in acceptance, not influenced by Share 35.

Statistical analysis

The primary outcome was whether an organ offer was accepted (yes/no). We used mixed-effects logistic regression models with patient- and center-level random intercepts,

accounting for donor and recipient factors associated with organ offer acceptance and organ quality, including components of the donor risk index (DRI).^{2,8} These models were used to account for variability in acceptance rates across transplant centers after adjustment for recipient and donor characteristics among all included match runs, while also testing for heterogeneity among transplant centers. These random intercepts were included because individual patients are clustered within transplant centers, which could lead to correlated outcomes of patients within those clusters. This is distinct from a traditional fixed effect (i.e., gender, age) that has levels that are of primary interest, whereas random effects are considered as being selected from a much larger set of levels.⁹ Multi-level models were used because of the two levels of clustering: patients within centers, and individual patients themselves because of the potential to have multiple organ offers for the same patient. For example, the decision to accept an organ for a given patient may be correlated among patients within centers, and among individual patients with multiple offers.⁹ To determine whether there was among-center variability in acceptance rates, the null hypothesis was that there was no residual heterogeneity (e.g., after accounting for all of the covariates in the model, the acceptance rates among centers are statistically not different from one another). A p-value <0.05 suggested that there were significant differences in organ offer acceptance rates after adjusting for the observed covariates in the model.¹⁰ Adjusted center acceptance rates were then calculated using the output of the multivariable model (post-estimation commands in Stata 13.0) that standardized each center's observed acceptance rate to the expected rate based on the model.¹¹ These analyses only included centers with ≥ 25 organ offers in a given category to prevent biased results due to small sample sizes. Lastly, we focused on donor quality of offers using the donor risk index (DRI)¹² as well as other features highly associated with donor "quality" (donor age and whether donor was a donation after neurologic determination of death [DNDD; brain-dead] or donation after circulatory determination of death [DCDD]). The specific reason for organ refusal (donor refusal codes) was included in secondary analyses.^{8,13}

RESULTS

There were 25,619 unique adult patients ranked in the top five of at least one match run during the study period, of whom 8,552 (33.4%) reached an allocation MELD score ≥ 35 at least once. The demographic characteristics of waitlist candidates ranked in the top five of a match run while having an allocation MELD score ≥ 35 were not clinically different pre- vs post-Share 35 (Table 1). However, there were significant differences in the etiology of liver disease (p<0.001); notably 18.4% of patients with an allocation MELD score ≥ 35 had alcohol-induced liver disease pre-Share 35 compared to 24.2% post-Share 35 (Table 1). Of the waitlist candidates pre-Share 35 who achieved an allocation MELD score ≥ 35, the mean number of offers while ranked in the top 5 positions was 2.1 (SD: 1.2), compared with 2.9 (SD: 1.4) for allocation MELD score ≥ 35 waitlist candidates in the post-Share 35 era (p<0.001).

Overall organ offer acceptance rates pre- vs post-Share 35

Overall liver offer acceptance rates for adult patients ranked in the top five of a match run decreased in the post-Share 35 era. However, the unadjusted acceptance rates pre- vs post-

Share 35 varied based on donor characteristics and whether the liver offer was local (donor and recipient in same donor service area) or regional (donor and recipient in same region but different donor service area). The absolute decrease in unadjusted acceptance rates was most pronounced among regional offers of DNDD donors <60 years of age ('highest quality') and local DCDD offers, all of which had an absolute decrease in acceptance rates of ~10%, with less pronounced differences in acceptance rates for local offers and regional offers of older donors (Figure 1a).

When the reasons for organ declines were evaluated, there was an increase in the absolute number of declines for all major refusal categories, but the greatest relative increase was declines for refusal code 803, "Patient transplanted, transplant in progress, or other offer being considered," (Figure 1b).

In multivariable models, there were several donor and recipient factors that were associated with organ offer acceptance (Table 2). Liver offer acceptance rates were lower in areas with increased local competition (increasing number of transplant centers in a given donor service area; consistent with published literature⁸), lower rank on a match run, and whether the donor was in a different donor service area than the waitlist candidate; Table 2).

There was a significant interaction between Share 35 era and MELD category ($p<0.001$; Figure 1c). Using liver offers to patients with an allocation MELD score <35 in the pre-Share 35 era as the reference, there was a slight decrease in the probability of having an organ offer accepted post-Share 35 for a patient with an allocation MELD score <35 (OR: 0.90, 95% CI: 0.85–94). Pre-Share 35, a given liver offer was significantly **more likely to be accepted** for a patient with an allocation MELD score ≥35 (compared to a patient with an allocation MELD score <35; OR: 1.19, 95% CI: 1.11, 1.28). By contrast, liver offers to patients with a MELD score ≥35 in the post-Share 35 era were significantly **less likely to be accepted** (compared to a patient with an allocation MELD score <35; OR: 0.76, 95% CI: 0.71, 0.81; Figure 1c). Comparing offers to MELD score ≥35 patients, offers post-Share 35 were 36% less likely to be accepted compared to offers to MELD score ≥35 patients pre-Share 35 (OR: 0.64). There was no change in the probability of having an organ offer accepted for a Status 1 patient after Share 35 (OR: 0.94 comparing status 1 post- vs-pre Share 35; Figure 1c).

Organ quality of accepted versus declined organs based on MELD score and era

Organs that were accepted were significantly 'better' based on the objective DRI measure ($p<0.001$; significantly lower DRI values) across MELD categories and era (Figure 2). However, there was no clinically meaningful difference in the DRI of livers that were declined for patients with an allocation MELD score <35 in the pre- vs post-Share 35 era, or for those with an allocation MELD score ≥35 in the pre- vs post-Share 35 era (Figure 2).

Regional changes in organ offer acceptance rates

At the regional level, the changes in organ offer acceptance rates were not uniform across the 11 OPTN/UNOS regions. Importantly, regions 8 and 9 served as reference points as they had regional sharing to differing degrees prior to implementation of Share 35 (region 8

started regional sharing in 2007 for patients with a MELD score ≥ 29 while Region 9 utilizes a single candidate list). There was an absolute decrease in organ offer acceptance rates (post-Share 35 acceptance rate—pre-Share 35 acceptance rate) for patients with an allocation MELD ≥ 35 in every OPTN/UNOS region among all organ offers (Figure 3a). These changes were greater in regions 2, 3, 4, 5, 6, 7, and 11, compared to reference regions 8 and 9. This pattern was also seen among the “best” donors: DNDD < 60 years of age (Figure 3b; changes greater than region 9 in regions 2, 3, 4, 5, 6, 7, 10, and 11) and DNDD donors < 40 years of age (Figure 3c; changes greater than region 9 in regions 2, 3, 4, 5, 6, 7, and 11).

Among-center changes in acceptance rates based on allocation MELD score

There were significant changes in organ offer acceptance rates at the center level pre- vs post-Share 35, and these changes varied across centers ($p < 0.001$). These center-level changes in acceptance rates were also different for patients with an allocation MELD score < 35 and ≥ 35 . Of the 101 transplant centers that had ≥ 25 offers pre- and post-Share 35 for a MELD < 35 patient, 18 (17.8%) had an increase in their organ offer acceptance rates, while 83 (82.2%) had a decrease (Figure 4a). By contrast, of the 81 centers that had ≥ 25 offers pre- and post-Share 35 for a MELD ≥ 35 , only 1 (1.2%) increased its organ offer acceptance rates, while 80 (98.8%) had a decrease in their liver acceptance rates (Figure 4b).

DISCUSSION

Implementation of Share 35 was associated with a significant decrease in offer acceptances for patients with an allocation MELD score ≥ 35 but not for patients with an allocation MELD < 35 . The policy appears to have directly led to changes in organ acceptance behaviors, given that the changes in acceptance rates for patients with a MELD score ≥ 35 were significantly greater than Regions 8 and 9, which already had broader sharing, in 7 out of the 9 other regions. Beyond changes at the regional level, these changes varied among OPTN/UNOS regions and also among transplant centers within the same region.

Behavioral changes are important to understand for a number of reasons. First, they cannot be modelled in LSAM, even though behavior can be predicted, and is done in other fields (i.e., behavioral economics). Behavior change introduces instability in model prediction, which leads to potentially inaccurate predictions if the models do not represent actual clinical practice. However understanding how changes to allocation may actually affect behavior in the community allows us to better predict how future policies might impact behavior and thereby policy outcomes. In particular, these results may provide insight into how broader sharing proposals might actually perform and what might negatively impact the goals of the policy. Finally, understanding how policies influence behavior might assist in policy design to produce a more desirable final result.

There is a nascent body of literature exploring organ offer data in liver transplantation and variability in organ offer acceptance rates among transplant centers.^{3,8,13–15} However, only one prior publication evaluated the changes in organ offer acceptance rates in response to a change in an organ allocation policy.³ In their analysis, Washburn et al found that after Share 35, organ offer acceptance rates declined only for patients with an allocation MELD score ≥ 35 .³ This work highlighted important findings in behavioral changes after Share 35, but

had important limitations, including: a) a focus on all organ offers, regardless of rank position (which treats all organ declines equally); b) excluded regions 8 and 9, thus neglecting an important ‘control’ group for a pseudo difference-in-differences approach; c) only evaluate a single year of data; d) did not evaluate regional and center-level changes; and e) did not account for correlated outcomes among individual patients with multiple offers and centers receiving offers on behalf of multiple patients. Our study validates and expands the early data from Washburn et al³. Washburn et al showed a change in the odds ratio of accepting an organ for patients with an allocation MELD score ≥ 35 from 1.29 to 0.96 pre- vs post-Share 35, representing a relative odds ratio of 0.74 (0.96/1.29). Our data demonstrated a greater and also sustained change in behavior pre- vs post-Share 35 from 1.19 to 0.76 (relative odds ratio of 0.64), or a 10% absolute decrease in organ acceptance rates (Figure 1a). Although some of the difference may be related to the longer term follow-up or difference in methods, these data highlight a dramatic change in practice patterns after Share 35 that does not correct with time.

At the level of the OPTN/UNOS region, we saw that liver acceptance rates among all centers in a region decreased, and these region-wide decreases in acceptance rates were greater among seven out of the nine regions not previously in regional share agreements prior to the Share 35 policy (Regions 8 and 9 already had regional sharing). This suggests that changes in acceptance were directly attributable to the policy. Center level data reinforces these findings 99% of centers had a decrease for patients with an allocation MELD score ≥ 35 . This further suggests that Share 35 changed practice patterns beyond what had been suggested as better matching of donor and recipient. In favor of this fact is the unchanged DRI in both MELD <35 and MELD ≥ 35 transplant recipients.

Our observation that the greatest relative reason for decline was “Patient transplanted, transplant in progress, or other offer being considered” suggest that as patients receive additional offers, centers act more selectively to attempt to utilize the best potential offer for their patients. The DRI data was virtually unchanged pre- vs post-Share 35 for organs that were accepted or declined, and would suggest that in spite of increase offers, the ultimately used graft had similar quality to organs the center had previously declined. Thus, there is a cost to the system with respect to operational and logistical inefficiency without demonstrable benefit to the patient.

As our community considers further expansion to sharing, our findings present very relevant and have significant implications to the path. Our data would suggest that broader sharing will result in a greater number of declines by centers, leading to reduced operation efficiency. This would provide an explanation for LSAM predictions of increased turndowns and fewer transplants with the redistricting proposal.¹⁶ In addition, organ placement may take more time and will be subject to less certainty. Declining an organ with advanced notice, due to an actual or anticipated better offer is understandable and should not affect the allocation process. However, a late decline in response to receiving an alternative and ‘better’ organ (perceived or truly better) does have important ramifications that affect the logistics of organ placement (i.e., OPOs needing to rapidly place an organ) and could lead to more grave consequences (i.e., an organ being discarded because of a late decline and an inability to find a candidate in the desired time window). Unfortunately, the nature of match

run data prevents us from answering these specific questions that might lead to a better understanding of how decisions impact efficiency. Nevertheless, the results point to the need to consider behavioral changes in response to a policy, which currently are not considered from current liver transplant policy development.

These data demonstrate important changes in clinician behavior in response to a policy that must be considered when designing and simulating the impact of future policies. Prior work by our group demonstrated organ offer acceptance rates were lower in donor service areas with multiple transplant centers, compared to single-center donor service areas, contrary to what many thought.⁸ Whether adding more centers to areas of organ sharing will lead to an additional impact is unclear. We had hypothesized that these findings were explained by competition changing behavior in order to maximize outcomes for patients not ranked at the top of the list, while still allowing the sickest patients to be transplanted. Unfortunately we demonstrated that the behavior or organ selection appeared detrimental to some patients, as patients at the top of the waitlist at centers with lower acceptance rates had higher mortality, despite having offers while the patients were active on the list prior to their death.⁸

This analysis did have limitations. The available data only include the date of the organ offer, and not the time. Furthermore, it does not include whether a patient initially had >1 provisional acceptance, and subsequently declined an organ and/or had simultaneous offers. For this reason, we cannot make firm conclusions as to why an organ offer was declined. However, that organ declines decreased as a result of the policy was the main focus of the analyses. Second, there may be other factors beyond those available in the dataset that are markers of organ quality. While this may be true, the similar DRI of organs that was accepted or declined pre- vs post-Share 35 suggest the overall organ quality did not change substantially. Third, we could not assess other factors that may have influenced organ declines at the center level (i.e., new surgical teams). Despite this, it would not explain the dramatic among-center variability.

Our current system of policy assessment relies on LSAM to predict the impact of changes in allocation and distribution policy. Unfortunately, LSAM does not account for behavioral changes.¹⁷ The behavior changes that are evident with Share 35 introduce significant uncertainty as to LSAM's ability to predict the outcomes of future policy changes. Behavior changes among centers need to be addressed if broader sharing through redistricting were enacted. Under the current 8-district redistricting proposal, the largest district would have 38 centers, and this district would perform 25% of all liver transplants in the US.¹⁶ Whether a potential and unanticipated change in acceptance behavior, which would not be anticipated by LSAM, appears likely based upon the data we outline above. Variable organ acceptance might present a logistical nightmare for the OPOs operating within the system and an unruly process could increase discard rates and thus decreased the total number of transplant nationally.

Acknowledgments

Grants and Financial Support:

1. David Goldberg: K08 DK098272

2. This work was supported in part by Health Resources and Services Administration contract 234-2005-37011C. The HRSA contract 234-2005-37011C is the funding sponsor for OPTN/UNOS who provided the transplant data used for this study, but did not play a role in the study.

Abbreviations

OPTN	Organ Procurement and Transplantation Network
MELD	Model for End-Stage Liver Disease
UNOS	United Network for Organ Sharing
HCC	Hepatocellular carcinoma
DRI	Donor risk index
LSAM	Liver Simulated Allocation Model

References

1. Sharma P, Schaubel DE, Gong Q, Guidinger M, Merion RM. End-stage liver disease candidates at the highest model for end-stage liver disease scores have higher wait-list mortality than status-1A candidates. *Hepatology*. 2012; 55(1):192–198. [PubMed: 21898487]
2. Nicolas CT, Nyberg SL, Heimbach JK, et al. Liver Transplantation after Share 35: Impact on Pre- and Post-Transplant Costs and Mortality. *Liver Transpl*. 2016
3. Washburn K, Harper A, Baker T, Edwards E. Changes in liver acceptance patterns after implementation of Share 35. *Liver transplantation*. 2016; 22(2):171–177. [PubMed: 26437266]
4. Kim WR, Lake JR, Smith JM, et al. Liver. *American journal of transplantation*. 2016; 16(Suppl 2): 69–98. [PubMed: 26755264]
5. [Accessed November 7, 2016] LSAM Users Guide: Version 2014. <http://srrt.org/sam/content/LSAM.pdf>
6. Chow EK, Massie AB, Luo X, et al. Waitlist Outcomes of Liver Transplant Candidates Who Were Reprioritized Under Share 35. *American journal of transplantation*. 2016
7. OPTN/UNOS Policies and Bylaws.
8. Goldberg DS, French B, Lewis JD, et al. Liver transplant center variability in accepting organ offers and its impact on patient survival. *J Hepatol*. 2016; 64(4):843–851. [PubMed: 26626495]
9. [Accessed November 11, 2014] Experimental Design and Analysis. 2014. <http://www.stat.cmu.edu/~hseltman/309/Book/Book.pdf>
10. Goldberg DS, French B, Abt PL, Gilroy RK. Increasing the Number of Organ Transplants in the United States by Optimizing Donor Authorization Rates. *Am J Transplant*. 2015
11. Normand S-LT, Shahian DM. Statistical and Clinical Aspects of Hospital Outcomes Profiling. 2007:206–226.
12. Feng S, Goodrich NP, Bragg-Gresham JL, et al. Characteristics associated with liver graft failure: the concept of a donor risk index. *American journal of transplantation*. 2006; 6(4):783–790. [PubMed: 16539636]
13. Lai JC, Feng S, Roberts JP. An examination of liver offers to candidates on the liver transplant wait-list. *Gastroenterology*. 2012; 143(5):1261–1265. [PubMed: 22841780]
14. Lai JC, Feng S, Vittinghoff E, Roberts JP. Offer patterns of nationally placed livers by donation service area. *Liver transplantation*. 2013; 19(4):404–410. [PubMed: 23447450]
15. Volk ML, Goodrich N, Lai JC, Sonnenday C, Shedden K. Decision support for organ offers in liver transplantation. *Liver transplantation*. 2015; 21(6):784–791. [PubMed: 25779757]
16. Organ Procurement and Transplantation Network. [Accessed September 2, 2016] Redesigning Liver Distribution Proposal Overview. 2016. <https://optn.transplant.hrsa.gov/governance/public-comment/redesigning-liver-distribution/>

17. [Accessed November 1, 2016] Liver Simulated Allocation Model User's Guide. <http://srtr.org/sam/content/LSAM.pdf>

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Figure 1.

a. Figure 1a: Changes in unadjusted acceptance rates by donor quality and share type

i. Legend: ■ Pre-Share 35
■ Post-Share 35

b. Figure 1b: Reason for declines of organ offers to patients with an allocation MELD score 35 in the pre- and post-Share 35 eras

i. Legend: ■ Pre-Share 35
■ Post-Share 35

c. Figure 1c: Forest plot of odds ratios from multivariable model for organ offer acceptances based on allocation MELD score and era

Figure 2.

Donor risk index of liver offers pre- and post-Share 35 based on allocation MELD score of patient and organ offer decision

Figure 3.

a. Figure 3a: Among-region changes in unadjusted acceptance rates pre- vs post-Share 35 by allocation MELD score for all deceased-donors

b. Figure 3b: Among-region changes in unadjusted acceptance rates pre- vs post-Share 35 by allocation MELD score for all brain-dead deceased-donors <60 years of age

c. Figure 3c: Among-region changes in unadjusted acceptance rates pre- vs post-Share 35 by allocation MELD score for all brain-dead deceased-donors <40 years

d. Legend

- acceptance rates for allocation MELD < 35
- acceptance rates for allocation MELD 35
- acceptance rates for Status 1

Figure 4.

a. Figure 4a: Changes in adjusted center-level liver acceptance rates pre- vs post-Share 35 for patients with an allocation MELD score <35

- i. Note: Each dot represents the change in a center's adjusted liver acceptance rates (Adjusted acceptance rate for patients with an allocation MELD score <35 post-Share 35) – (Adjusted acceptance rate for patients with an allocation MELD score <35 pre-Share 35)

b. Figure 4b: Changes in adjusted center-level liver acceptance rates pre- vs post-Share 35 for patients with an allocation MELD score ≥ 35

- i. Note: Each dot represents the change in a center's adjusted liver acceptance rates (Adjusted acceptance rate for patients with an allocation MELD score ≥ 35 post-Share 35) – (Adjusted acceptance rate for patients with an allocation MELD score ≥ 35 pre-Share 35)

Table 1

Characteristics of patients ranked in the top 5 of a match run with an allocation MELD score ≥ 35 in the pre- vs post-Share 35 era, N=8,552

Variable	Pre-Share 35, n=3,446*	Post-Share 35, n=5,152*	P-value
Age at match run, median (IQR) [†]	55.9 (49.0–61.0)	56.0 (48.0–61.9)	0.23
Male gender	2,150 (62.4)	3,103 (60.2)	0.04
Race/ethnicity			0.61
White	2,210 (64.1)	3,327 (64.6)	
Black	362 (10.5)	546 (10.6)	
Hispanic	693 (20.1)	983 (19.1)	
Asian	136 (4.0)	213 (4.1)	
Other	45 (1.3)	83 (1.6)	
Etiology of liver disease			<0.001
Hepatitis C	1,262 (36.6)	1,562 (30.3)	
Alcohol-induced liver disease	633 (18.4)	1,246 (24.2)	
NASH/Cryptogenic	561 (16.3)	920 (17.9)	
Autoimmune hepatitis	160 (4.6)	270 (5.2)	
Primary sclerosing cholangitis	170 (4.9)	235 (4.6)	
Primary biliary cirrhosis	116 (3.4)	187 (3.6)	
Hepatitis B	98 (2.8)	120 (2.3)	
Other	446 (12.9)	612 (11.9)	
History of prior transplant	200 (8.0)	304 (7.9)	0.93
Received HCC exceptions	57 (1.7)	96 (1.9)	0.47
Received non-HCC exceptions	106 (3.1)	205 (4.0)	0.03
Calculated MELD score at listing	28 (18–37)	29 (18–37)	0.13
Listed for simultaneous liver-kidney transplant	691 (20.1)	972 (18.9)	
Transplanted	2,514 (73.0)	3,849 (74.7)	0.07
Died or became too sick	831 (24.1)	1,112 (21.6)	0.006

* 46 patients included in both pre-Share 35 and post-Share 35 cohorts

[†] Defined as age the first time a patient was ranked in the top 5 of a match run with an allocation MELD ≥ 35

Table 2

Other actors associated with organ offer acceptance for waitlist candidates ranked in the top five position of a match run from 1/1/11–12/31/15*

Variable	Multivariable odds ratio *	P-value
Recipient factors		
Age at match run [†]	1.00 (0.99–1.01)	0.38
Male sex	1.26 (1.21–1.31)	<0.001
HCC exception points	1.08 (1.02–1.15)	0.009
‘Other’ exception points ⁴	0.87 (0.81–0.93)	<0.001
Re-transplant candidate	0.49 (0.46–0.53)	<0.001
Match run rank		<0.001
1	Reference	
2	0.82 (0.78–0.86)	
3	0.69 (0.65–0.73)	
4	0.55 (0.51–0.58)	
5	0.45 (0.42–0.48)	
Listed for SLK	0.44 (0.42–0.47)	<0.001
Donor factors		
Age [‡]	0.86 (0.85–0.87)	<0.001
Donor race/ethnicity		<0.001
White	Reference	
Black	1.03 (0.98–1.08)	
Hispanic	0.99 (0.93–1.06)	
Asian	1.13 (1.00–1.27)	
Other	0.81 (0.70–0.94)	
Donor cause of death		<0.001
Anoxia	Reference	
CVA/stroke	1.46 (1.39–1.54)	
Head trauma	1.40 (1.33–1.47)	
CNS tumor	1.22 (0.92–1.62)	
Other	1.08 (0.94–1.25)	
DCD donor	0.23 (0.21–0.25)	<0.001
Geographic factors		
Local center competition		<0.001
1-center DSA	Reference	
2-center DSA	0.96 (0.74–1.25)	
3-center DSA	0.69 (0.53–0.90)	
4-center DSA	0.48 (0.34–0.66)	
Donor share type		<0.001
Local	Reference	
Regional	0.59 (0.56–0.63)	
National	0.04 (0.03–0.06)	

* Primary exposures of model were allocation MELD, Share 35 era, and the interaction of these two variables (Figure 1). Model was mixed-effects logistic regression model with individual center-level random intercepts. The $p < 0.001$ indicated that there was residual heterogeneity between transplant centers after accounting for the patient demographic and geographic factors in the multivariable model based on the test of random center effects. Recipient race/ethnicity was forced into the model but not shown because it was not significant ($p > 0.05$)

[†] Per 5-year increase in age

[‡] Other exception points included increased prioritization granted for patients for conditions other than HCC, such as hepatopulmonary syndrome, recurrent cholangitis, complications of portal hypertension, etc.

HCC=hepatocellular carcinoma; CVA=cerebrovascular accident; CNS=central nervous system; DCD=donation after cardiac death; DSA=donor service area