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Exception point applications for 15 points: An unintended consequence of the Share 15 policy

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Abstract

In 2005, the United Network for Organ Sharing (UNOS) adopted the Share 15 policy, intending to improve organ allocation by facilitating transplants for local and regional patients with Model for End-Stage Liver Disease (MELD) scores of 15 or greater. There has been concern that the lack of standardization in the use of exception points potentially diminishes the benefits of this policy. We reviewed all applications for 15 exception points submitted through UNOS from January 1st, 2005 through March 14th, 2011 (of note, there were only 5 applications for 15 MELD exception points submitted prior to initiation of the Share 15 policy). A total of 452 applications were submitted for 301 patients. There was significant regional variability, with regions 3 and 10 submitting 72.1% of all applications. Over one-quarter (31.0%) of applications specifically requested exception points to make a patient eligible for a local, regional, or higher-risk organ. 74.1% (223/301) of patients had all applications accepted, of which 72.2% were ultimately transplanted compared to 54.0% with all applications denied ($p=0.006$). Overall, 197 (65.4%) applicants were transplanted with a deceased donor organ, of which 80.2% had a native MELD score at transplantation less than 15. These analyses demonstrate several important practice changes that have occurred as a consequence of the implementation of the Share 15 policy. Since 2005, there has been a marked increase in the number of applications for 15 exception points, with significant regional variability in their use and lack of standardization in their approval.

Keywords

liver transplantation; organ allocation; regional review boards

Introduction

Since 2002, the Model for End-Stage Liver Disease (MELD) score has been used to prioritize patients listed for liver transplantation in the United States. In the first two years of MELD-based allocation, it was noted that 24% of transplant recipients had a laboratory MELD score less than 15 at the time of transplantation, with geographic differences in the distribution of such patients (1, 2). This was concerning, as patients with MELD scores under 15 also have a greater risk of dying one-year post-transplant compared with remaining on the waitlist (1). In response, in 2005, the Organ Procurement and Transplantation Network and the United Network for Organ Sharing (UNOS) adopted the Share 15 policy with the goal of improving regional organ allocation. It states that organs must first be

offered to patients with MELD scores of 15 or greater locally and then regionally, before making them available to local patients with MELD scores under 15 (3).

Although organ allocation is primarily driven by the MELD score, transplant centers may apply for exception points from their regional review boards (RRBs) for patients whose MELD score underestimates their true risk of waitlist mortality. Despite the MELD Exceptional Case Guideline study group publishing evidence-based consensus recommendations regarding the granting of exception points (4), regional variation in the application of such points still exists (2).

Since the implementation of Share 15, there has not been a focused evaluation of exception point applications in response to this policy. We hypothesized that the inconsistency in the utilization of exception points and the lack of standardization in their allocation could mitigate the potential benefits of a regional sharing policy. The goal of the study was to provide a greater understanding of exception point applications since the adoption of the Share 15 policy, and to highlight their consequences in the current organ allocation system by: a) determining if there have been changes in the application for 15 MELD exception points since the initiation of the Share 15 policy; b) describing the patterns of applications for, and acceptance of exception point applications for 15 MELD exception points; and c) determining the impact of applications for 15 MELD exception points on the utilization of organs in “low-MELD” patients.

Methods

Study Population

All analyses were based on Organ Procurement and Transplantation Network data from January 1st, 2005 through March 14th, 2011. The start date of January 1st, 2005 was chosen as it was the initiation date of the current regional Share 15 policy. Prior to this date there were only 5 applications for 15 MELD exception points between 2/27/2002 and 12/31/2004. We included all adult waitlisted candidates 18 years of age at the time of listing who applied for 15 exception points to an RRB. We only included initial transplant candidates, and excluded patients listed for re-transplantation, as: 1) the MELD score has only been validated to predict the waitlist mortality of patients listed for initial transplantation (5); and 2) the cutoff of MELD less than 15 as an indicator of higher post-transplant mortality focused on patients listed for initial transplantation (1). We identified exception point applicants by analyzing a UNOS Standard Transplant Analysis and Research file that included the requested exception score, the reason for exception point application (based on 11 possible codes), the entire narrative submitted by the transplant center, and the result of the application. We included only candidates who had at least one exception point application for 15 points (UNOS variable *request score* was equal to 15).

Each narrative was reviewed in detail (T.B.), with a random sample of 10% receiving a secondary review (D.G.). Based on the individual narrative, each application was coded into one of 15 categories, per Table 1. For those narratives requesting exception points for greater than one condition, the application was categorized based on the predominant clinical condition described in the narrative.

During the review of the narratives, it was noted that a number of applications specifically requested exception points to achieve a MELD score high enough for the patient to receive an organ. These were categorized into: a) requesting points to make a patient “eligible” or “considered” for a transplant; b) requesting points to have “access to,” or to “keep organs” “local;” c) requesting points to have access to “regional” organs; or d) requesting points to have access to “extended criteria” (“high donor risk index”) organs. Each of these requests

was made to allow the candidate to be assigned the 15 points needed to receive a local or regional organ under the Share 15 policy, without the organ first having to be offered to a regional candidate with a MELD score under 15. Thus, they were aggregated into the category: “Asked for points to allow patient to receive organ under Share 15 policy.”

Outcome

The primary outcome was the result of the application for exception points. The application had five potential outcomes based on the decision by the RRB: request approved, request denied, withdrawn, indeterminate, or not approved in 21 days. We dichotomized the results of applications to either approved vs. denied (which included all other possible outcomes). In evaluating the outcome of transplantation, only recipients of deceased donor organs were counted to account for organs allocated based on match MELD scores.

Statistical Analysis

Wilcoxon rank-sum and Kruskal-Wallis tests were used for continuous variables, and chi-square tests for categorical variables, given the non-normal distribution of the data. We compared application acceptance rates between: a) different UNOS regions and b) different categories of reasons for exception point applications. In assessing regional variation, we excluded region 9, as it is the only region with a single list, and the implications of Share 15, and the need to apply for exception point to keep organs local, would not apply.

We sought to determine if there were differences in waitlist outcomes, based on the acceptance or denial of an exception application. As candidates may have applied for an exception more than one time, with differing results each time, patients were categorized as: a) all applications accepted; b) all applications denied; or c) at least one application accepted and one application denied.

Waitlist candidates may have sought additional exception points after applying for 15 points, or may have had progressive liver disease with a laboratory MELD score rising to greater than 15. To estimate the proportion of patients subsequently transplanted with a MELD score of greater than 15, transplant recipients were dichotomized by their match MELD at transplantation: greater than 15 compared to equal or less than 15. We calculated the donor risk index (DRI) for transplant recipients using the formula established by Feng et al (6).

We measured socioeconomic factors using residential zip code-level poverty, a measure used in prior transplantation literature (7). Using zip code data provided in UNOS, we measured neighborhood poverty by estimating the proportion of individuals residing below the federal poverty level within a five-digit zip code (8). We compared socioeconomic data for MELD 15 exception applicants to those of the entire waitlist pool during the study period.

All calculations were made using Stata Version 12 (College Station, Texas). This study received exempt review from the Institutional Review Board at the University of Pennsylvania.

Results

Baseline demographics

A total of 452 applications for 15 exception points among 301 patients were submitted between January 1st, 2005 and March 14th, 2011, with a mean of 1.7 ± 1.2 applications per patient. Table 2 provides an overview of patient demographics. Compared to the general pool of waitlisted candidates, candidates applying for 15 exception points were less likely to

be male (57.5% vs. 64.6%; $P=0.01$) and more likely to be white (82.1% vs. 73.7%; $P<0.001$). The primary diagnoses of applicants for 15 MELD exception points also varied significantly from the overall pool, most notably for hepatitis C (20.6% vs. 37.0%; $P<0.001$), cholestatic liver disease (19.6% vs. 7.8%; $P<0.001$), alcoholic liver disease (8.3% vs. 16.1%; $P=0.004$), and polycystic liver disease (6.6% vs. 0.4%; $P<0.001$). During the study time period, there was a gradual increase in the number of applicants, and applications per year (Table 3). With regards to socioeconomic factors, when compared to the general pool of waitlist candidates, a significantly greater proportion of MELD 15 exception point applicants lived in neighborhoods with fewer than 10% of the population living below the federal poverty level. On the other hand, a significantly lower proportion lived in neighborhoods with greater than 20% living above the poverty level (Supplementary Table 1).

Reasons for exception point applications

The primary reasons for exception point applications and outcomes are detailed in Table 4. Four of 15 reasons accounted for more than half of all applications: encephalopathy (15.9%), hepatocellular carcinoma (15.5%), refractory ascites (11.1%), and recurrent cholangitis (9.5%). There was no statistically significant difference in the application approval rates for each category ($p=0.61$) or in the percentage transplanted ($p=0.11$).

The median laboratory MELD score of the entire cohort at the time of applying for exception points was 11 (interquartile range (IQR): 9–14). Using the formula by Kim et al (9), the calculated MELD-Na for the entire cohort was 13 (IQR: 10–17). For the group of patients with ascites or hydrothorax, the median laboratory MELD was 11 (IQR: 10–13), whereas the median MELD-Na was 16 (IQR 12–18).

Of the 452 applications, 148 (31.0%) specifically requested exception points to allow a patient to receive an organ under the Share 15 policy (see Methods). There was variability across regions in the use of this specific language in the narratives. As an example, 59 of 196 (30.1%) narratives in region 3 made specific mention of applying for exception points to receive an organ under the Share 15 policy, as compared with 13/130 (10.0%; $P<0.001$ comparing region 3 vs. region 10) in region 10.

Regional variation in exception point applications

There were significant regional differences in the number of applicants and applications (Table 5, excluding region 9, as noted in Methods section). 208 (69.1%) applicants were from regions 3 and 10, as opposed to 6 (2.0%) from regions 1 and 5. According to UNOS and Organ Procurement and Transplantation Network data as of 3/14/2011, excluding region 9 (see Methods section), 17.7% of all waitlisted candidates were from regions 3 and 10, as compared with 33.3% from regions 1 and 5. There was no correlation between the proportion of patients listed with an initial laboratory MELD score of less than 15, and the proportion of applications for 15 MELD exception points in a region. In fact, region 3 had the lowest proportion of candidates with an initial listing laboratory MELD score under 15, while region 10 had the fourth highest (data not shown). The overall approval rate was 81.0%, again with significant regional differences. Among regions with greater than 10 applications, the approval rate ranged from less than 70% (regions 7 and 10) to over 90% (region 3).

Of the 301 waitlist candidates applying 15 exception points, 292 (97%) had data available on their listing organ-procurement organization (OPO) and donor service area (DSA). Of the 292 with available data, 149 (51.0%) were listed in a non-competitive DSA (single-center DSA), while 143 (49.0%) were listed in a competitive DSA (multi-center DSA). Of the 143

listed in a competitive DSA, 52 (36.4%) were listed in a DSA with 2 centers, 33 (23.1%) with 3 centers, 20 (14.0%) with 4 centers and 38 (26.6%) in a DSA with at least 5 centers.

Outcomes of exception point applicants

Among the 301 applicants, 223 (74.1%) had all applications accepted, while 63 (20.9%) had all denied (Table 6). Overall, 197 (65.4%) applicants received a transplant, of which 192 (97.5%) received a deceased donor organ. 139 (74.3%) organs were local shares, while 31 (16.6%) were regional, and 17 (9.1%) national.

The median DRI was 1.56 (IQR: 1.16–1.86) for all candidates submitting exception point applications. When analyzed by region, the median DRI was higher for exception point applicants in regions 2, 3, 6 and 10 when compared to all initial transplant recipients. However, these differences did not reach statistical significance ($p=0.052$ in region 3, $p=0.09$ in region 10, and only 6 exception point applicants were transplanted in total between regions 2 and 6 limiting statistical testing).

During the study period, a similar proportion and number of patients each year (29.0–34%, $p=0.94$ comparing years 2005–2011) were transplanted with a laboratory MELD score under 15 at the time of transplantation. On the regional level, the number of transplant recipients over time with laboratory MELD scores under 15 was unchanged except for an increased proportion in region 8, and a decreased proportion in region 10. After excluding all transplant recipients who ever received exception points of any amount there was a significantly lower proportion of patients transplanted each year with a laboratory MELD score of less than 15 (16.2% in 2005 to 7.6% in 2010; $p<0.001$ comparing years 2005–2011).

Among applicants with all applications approved, 158 (72.1%) were transplanted compared with 34 (54.0%) and 5 (35.7%) of those with all of their applications denied, or with applications both approved and denied, respectively ($p=0.001$ comparing three groups). The risk of waitlist removal for death or clinical deterioration was not different between those with all applications approved compared to those with all applications denied (19/223, 8.5% vs. 9/63, 14.3%; $P=0.36$). The median laboratory and match MELD scores at transplantation were similar among those with all of their applications approved or denied.

The proportion of all applicants transplanted was similar across the UNOS regions (data not shown). Of the four regions who transplanted at least 15 of these exception point applicants (regions 2, 3, 10, and 11), all had a median match MELD at transplantation of 15. Of the 197 applicants who received a deceased donor organ, 70.1% (138/197) had a match MELD of 15 or less, and 80.2% (158/197) had a laboratory MELD score under 15 at the time of transplantation.

The outcomes of exception point applications in competitive compared to non-competitive DSAs were similar ($p = 0.53$). Of the 149 applicants in non-competitive DSAs, 71.8% had all of their applications accepted, 23.5% had all of them denied, and 4.7% had at least one accepted and one denied. In competitive DSAs, these numbers were 76.2%, 18.2% and 5.6% respectively. The rates of transplantation were not significantly different for waitlist candidates in competitive compared to non competitive DSAs. 102 (68.5%) applicants from non-competitive DSAs were ultimately transplanted compared to 93 (65.0%) in competitive DSAs ($p=0.54$).

Discussion

This is the first study to demonstrate several important consequences of the Share 15 policy. Since January 1st, 2005, there have been over 450 applications for 15 MELD exception points, a phenomenon which essentially did not exist prior to the implementation of the Share 15 policy. These applications were disproportionately concentrated in two regions (3 and 10). Over 80% of all applications were approved and 65.4% of patients were transplanted. Most importantly, none of these applicants met published guidelines for conditions justifying automatic exception points (4). There is no doubt that physicians should not be faulted for applying for exception points and acting on their patients' behalf. However, under the current system, these patients can apply for exception points, and be transplanted with low MELD scores, despite the substantial number of patients dying in areas of the country with significantly higher MELD scores. With a national Share 15 policy being considered, it is possible that this phenomenon of 15 MELD exception points may be utilized more frequently in the future if such a policy is enacted.

In 2005, the Share 15 policy was enacted with the goal of improving organ allocation to those more likely to derive a significant survival benefit from transplantation. Simulations suggested that this policy would decrease the number of transplants in low-MELD patients, benefiting the total population of waitlist candidates. Unfortunately, these simulations could not predict changes in human behavior, as the total number of patients transplanted nationally with laboratory MELD scores under 15 at transplantation were unchanged over time. Additionally, excluding region 9, only 15/55 OPOs are single-center OPOs. Yet despite these centers representing a minority of over 100 liver transplant centers in the US, half of the applicants for 15 MELD exception points were listed in one of these single-center OPO. While the data do not allow us to definitively conclude all the reasons why these centers applied for 15 MELD exception points, this aspect of the data would suggest that one motivation is to avoid the sharing of organs.

It is known that in some patients the physiologic MELD score does not accurately represent waitlist mortality. The MELD Exceptional Case Guideline study group publication has helped identify a few, specific circumstances in which automatic exception points are recommended (4). However, excluding patients with HCC within Milan criteria, metabolic disease, and hepatopulmonary syndrome, the granting of points for waitlisted candidates applying for exception points is based on a free-form narrative that is assessed by a RRB. There has been limited evidence-based guidance on how to approach the more common reasons for application. For example, there is little data to support that patients with cholestatic liver disease are currently disadvantaged by the MELD system (10) and patients with complications such as recurrent cholangitis should meet specific requirements in order to receive additional MELD points. Other conditions though, such as polycystic liver disease, are associated with quality of life improvements after liver transplantation, although not necessarily with an increased pre-transplant mortality risk (11). These are therefore decisions which require careful evaluation as they may have important consequences—as demonstrated by Massie et al, patients who receive exception points have a significantly lower risk of waitlist mortality and greater odds of transplantation (12). If not judiciously selected, these patients could potentially disadvantage others who remain waitlisted in areas with different exception point practices.

The increased use of 15 MELD exception points reflects the greater trend in the use of exception points overall in candidates waitlisted for liver transplant (13). The data demonstrated a decrease in the number patients transplanted with laboratory MELD scores under 15 over time only when all exception point applicants were excluded. But, the total number of organ recipients with low MELD scores was unchanged since the inception of

Share 15. This general trend in the use of exception points is likely the product of a variety of factors, such as an increase in severity of disease of waitlisted candidates overall, as well as an increase in the prevalence of hepatocellular carcinoma over time.

However, our research suggests that the specific increase in 15 MELD exception points may be more directly related to the Share 15 policy for two reasons. First, prior to January 1st, 2005, there were only 5 applications for 15 MELD exception points compared to 452 after, with a progressive increase over time. Second, 31% of applications for 15 MELD exception points specifically requested points to either make patients considered for a transplant, to “keep organs local”, to have access to “regional organs”, or to have access to “extended criteria donors.” In reviewing this data, it is difficult to argue that the rise in applications for 15 MELD exception points was not a direct product of the Share 15 policy.

This study also demonstrates that significant regional variation exists in the requests for MELD exception points under the Share 15 policy. To some extent, this is not surprising; as it is in the “low MELD” regions that obtaining a score of 15 might increase the probability of transplantation the most. This is especially true if exception points are sought with the specific aim to access extended criteria donor organs. While it must be reiterated that physicians should not be blamed for attempting to provide comprehensive care for their patients, this could have important ramifications if a national Share 15 policy is created in the future. An increase in the trend towards applying for 15 MELD exception points could further exacerbate these regional disparities in access to transplantation. Advocating for the best interest of an individual patient may conflict with efforts to improve the outcomes of waitlisted candidates as a group.

To promote fairness and equity in the allocation of organs a more standardized approach should be used in the evaluation of exception point applications. For example, a national review board, able to address requests from any part of the country, could help minimize the regional variation seen in the use of exception points. In addition, the development of more comprehensive guidelines for both physicians applying for points and the review boards evaluating requests is needed, especially for the common reasons for exception point applications (encephalopathy, ascites, variceal bleeding, etc.). For patients with ascites or hepatic hydrothorax, our data suggest that 15 MELD exception points could be used effectively if formal consideration of the MELD-Na is included. Finally, more research is needed to better identify those conditions for which the MELD score does not adequately estimate waitlist mortality.

Interestingly, the majority of patients who received 15 exception points were transplanted at MELD scores at or below 15. This suggests that few additional exception points were granted and that the laboratory MELD did not substantially increase between the time of application approval and the time of transplantation. In addition, the risk of death or waitlist removal was not significantly different between patients whose applications were approved or denied. Thus, there may not have been significant progression of disease during this period and patients were possibly given priority for transplant when they did not actually have a significantly increased mortality risk. Finally, the average DRI of all patients receiving 15 exception points was not significantly different than the national average for all transplanted patients (1.41; IQR 1.13–1.73), and when analyzed by region the differences in median DRI did not reach statistical significance. This suggests that higher risk organs were not more frequently transplanted in these candidates.

This study had several limitations. First, the UNOS Standard Transplant Analysis and Research file from which the data was extrapolated can contain incomplete data. However, unlike exception points for hepatocellular carcinoma, in order for these applications for 15

points to be reviewed by the RRB, each patient's narrative is mandatory, therefore it is unlikely that significant information was missing from our data collection. Since these narratives were submitted to UNOS by individual transplant centers, the specifics of how each RRB determined which candidates should receive exception points is largely unknown: only the final decision was available for review. For example, many applications were submitted for more than one reason. While we selected the primary reason in our review, it is expected that for many applicants a combination of factors were considered by the RRBs in determining whether points should be granted. Furthermore, it is likely that patients with multiple complications of cirrhosis have increased waitlist mortality, though this has not been widely studied. Regarding the patients with low laboratory MELD scores at transplant, it is possible that patients who received exception points still derived a significant survival benefit from liver transplantation and had a waitlist mortality risk that was different from the overall pool of low MELD candidates. While we can infer that the increase in the use of exception points since the creation of Share 15 has potentially affected organ sharing, whether actual hazards exist as a result of this has yet to be determined. Finally, with respect to the socioeconomic differences in patients applying for 15 MELD exception points, the use of neighborhood poverty was used as a surrogate and may not truly represent patient socioeconomic data. Continued research efforts are needed in order to gain a more comprehensive understanding of the differences in socioeconomic backgrounds in these patients.

The authors recognize that the total number of patients applying for 15 MELD exception points is small; however we believe the implications are significant for a number of reasons. First, there may be a greater risk associated with transplanting low MELD patients, as compared with their remaining on the waitlist. Second, transplanting low MELD patients with exception points, even in small numbers, diverts organs from those waitlist candidates with high MELD scores with the highest risk of waitlist mortality. Third, as mentioned, the use of 15 MELD exception points may increase if a National Share 15 policy is enacted. Lastly, the implications and scale of this data (60 patients per year) is similar to the potential impact of several other policies being strongly considered by the UNOS Liver and Intestinal Organ Transplantation Committee. The impact of limiting the transplants in these 15 MELD exception patients (over 30 transplants per year) is akin to the potential gains associated with the proposed National Share 15 policy, which could reduce waitlist deaths by 25 per year (14), or the Regional Share 35 policy, which could prevent an additional 32 deaths per year (15). Therefore, given the continued shortage of this therapeutic modality, it is paramount that organs be allocated in a system that equitably addresses both patient need and potential benefit. In providing an assessment of one specific aspect of organ sharing, we anticipate and encourage continued evaluation and research in both current and future liver transplant allocation policies.

In conclusion, the implementation of the UNOS Share 15 policy has given way to a marked increase in applications for 15 exception points. Though there is significant regional variability in the utilization of this practice, which may be partly explained by regional differences in median MELD at transplantation, there is currently no standardization of the review and point allocation process across, or even within, different regions. Most importantly, a number of patients continue to be transplanted with low MELD scores, many with the help of these additional exception points, who may have greater mortality risk as a result of transplantation. Without any interventions in the current state, there remains a risk of continued disparities in the allocation of organs in the United States. These issues will be heightened if a national sharing program is enacted without a process in place to systematically address the issue of exception points.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations

MELD	Model for End-Stage Liver Disease
UNOS	United Network for Organ Sharing
RRB	regional review board
DRI	donor risk index
IQR	interquartile range
OPO	organ-procurement organization
DSA	donor service area

References

1. Merion RM, Schaubel DE, Dykstra DM, Freeman RB, Port FK, Wolfe RA. The survival benefit of liver transplantation. *Am J Transplant.* Feb; 2005 5(2):307–313. [PubMed: 15643990]
2. Roberts JP, Dykstra DM, Goodrich NP, Rush SH, Merion RM, Port FK. Geographic differences in event rates by model for end-stage liver disease score. *Am J Transplant.* Oct; 2006 6(10):2470–2475. [PubMed: 16939519]
3. Organ Procurement and Transplantation Network. [Accessed February 21, 2012] Policy 3.6: Allocation of Livers. Available at: http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_8.pdf
4. Freeman RB Jr, Gish RG, Harper A, Davis GL, Vierling J, Lieblein L, et al. Model for end-stage liver disease (MELD) exception guidelines: results and recommendations from the MELD Exception Study Group and Conference (MESSAGE) for the approval of patients who need liver transplantation with diseases not considered by the standard MELD formula. *Liver Transpl.* Dec; 2006 12(12 Suppl 3):S128–136. [PubMed: 17123284]
5. Wiesner R, Edwards E, Freeman R, Harper A, Kim R, Kamath P, et al. Model for end-stage liver disease (MELD) and allocation of donor livers. *Gastroenterology.* Jan; 2003 124(1):91–96. [PubMed: 12512033]
6. Feng S, Goodrich NP, Bragg-Gresham JL, Dykstra DM, Punch JD, DeRoy MA, et al. Characteristics associated with liver graft failure: The concept of a donor risk index. *Am J Transplant.* Apr; 2006 6(4):783–790. [PubMed: 16539636]
7. Patzer RE, Amaral S, Klein M, Kutner N, Perryman JP, Gazmararian JA, et al. Racial disparities in pediatric access to kidney transplantation: does socioeconomic status play a role? *Am J Transplant.* 2012; 12(2):369–78. [PubMed: 22226039]
8. U.S. Census Bureau American Fact Finder. [Search performed on July 5, 2012]. available from: <http://factfinder2.census.gov/faces/nav/jsf/pages/searchresults.xhtml?refresh=t>

9. Kim WR, Biggins SW, Kremers WK, Wiesner RH, Kamath PS, Benson JT, et al. Hyponatremia and mortality among patients on the liver-transplant waiting list. *N Engl J Med.* 2008; 359(10):1018–26. [PubMed: 18768945]
10. Goldberg D, French B, Thomasson A, Reddy KR, Halpern SD. Waitlist survival of patients with primary sclerosing cholangitis in the model for end-stage liver disease era. *Liver Transpl.* Nov; 2011 17(11):1355–1363. [PubMed: 21837735]
11. Kirchner GI, Rifai K, Cantz T, Nashan B, Terkamp C, Becker T, et al. Outcome and quality of life in patients with polycystic liver disease after liver or combined liver-kidney transplantation. *Liver Transpl.* Aug; 2006 12(8):1268–1277. [PubMed: 16741930]
12. Massie AB, Caffo B, Gentry SE, Hall EC, Axelrod DA, Lentine KL, et al. MELD Exceptions and Rates of Waiting List Outcomes. *Am J Transplant.* Sep 15.2011
13. Thuluvath PJ, Guidinger MK, Fung JJ, Johnson LB, Rayhill SC, Pelletier SJ. Liver transplantation in the United States, 1999–2008. *Am J Transplant.* 2010; 10(4 Pt 2):1003–19. [PubMed: 20420649]
14. OPTN/UNOS Liver and Intestinal Organ Transplantation Committee. [Accessed July 28, 2012] Concept document: Next steps toward improving liver distribution. Jan 4. 2011 Available at: http://optn.transplant.hrsa.gov/SharedContentDocuments/LiverConcept_123010.pdf
15. OPTN/UNOS Liver and Intestinal Organ Transplantation Committee. [Accessed July 28, 2012] At-a-Glance: Proposal for regional distribution of livers for critically ill candidates. Available at: http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_288.pdf

Table 1

Reasons for applications for exception points

Reason for application for exception points
Hepatocellular carcinoma
Recurrent bacterial cholangitis
Refractory ascites
Hepatic encephalopathy
Recurrent variceal bleed (esophageal and/or gastric)
Pruritus
Other liver tumors [†]
Spontaneous bacterial peritonitis
Refractory hepatic hydrothorax
Other [‡]
Portal vein or superior mesenteric vein thrombosis
Other gastrointestinal bleeding, not due to varices
Portopulmonary hypertension or hepatopulmonary syndrome
Symptomatic Polycystic liver disease

[†]Cholangiocarcinoma, hepatic adenoma, VIPoma, sarcoma, hemangioendothelioma, angiosarcoma, hemangioma, dysplasia w/o HCC, ductal cell atypia

[‡]Advanced age, TIPS infection, lower extremity edema, patient needing porto-caval hemitransposition, other technically challenging transplant, recurrent cholecystitis, chronic abdominal pain (not due to polycystic liver disease), patient needing or with history of coronary artery bypass surgery, biliary strictures (native liver), patient with history of abdominal aortic aneurysm repair, failure to thrive, recurrent pancreatitis, patient needing back surgery, systemic amyloidosis

Table 2

Demographic data on all adults(n=301)with at least one exception application for 15 points

Variable	
Age in years, Median (IQR)	54 (45–60)
Male Gender, N (%)	173 (57.5)
Race/Ethnicity, N (%)	
White	247 (82.1)
Black	30 (10.1)
Hispanic	18(6.0)
Asian	6 (2.0)
Primary diagnosis, N (%)	
Hepatitis C	62 (20.6)
Cholestatic	59(19.6)
NASH/Cryptogenic	45 (15.0)
Hepatocellular carcinoma	38 (12.6)
Alcoholic liver disease	25 (8.3)
Polycystic liver	20 (6.6)
Autoimmuneliver disease	8(2.7)
Hepatitis B	3 (1.0)
Other	41 (13.6)

IQR: Interquartile Range

NASH: Non-Alcoholic Steatohepatitis

Table 3

Number of applicants and applications per year

Year	Number of applicants (% total applicants)*	Number of applications (% total applications)
2005	35 (11.6)	36 (8.0)
2006	46 (15.3)	60 (13.3)
2007	40 (13.3)	61 (13.5)
2008	53 (17.6)	72 (15.9)
2009	69 (22.9)	114 (25.2)
2010	54 (17.9)	97 (21.5)
2011	4 (1.3)	12 (2.7)

* Based on the year the first application was submitted

Table 4

Reasons for exception point applications

Reason for exception application	Number of applications, N (%)	Applications approved, N (%) [*]	Asked for points to allow patient to receive organ under Share 15 policy [‡]	Number individual applicants	Applicants transplanted, N (%) [‡]
Encephalopathy	72 (15.9)	58 (80.6)	29 (40.3)	43 (14.3)	26 (61.9)
Hepatocellular carcinoma	70 (15.5)	56 (80.0)	19 (27.1)	63 (20.9)	52 (82.5)
Refractory ascites	50 (11.1)	37 (74.0)	19 (38.0)	39 (13.0)	21 (55.3)
Recurrent cholangitis	43 (9.5)	34 (79.1)	8 (18.6)	25 (8.3)	16 (64.0)
Pruritus	36 (8.0)	30 (83.3)	18 (50.0)	16 (5.3)	8 (57.1)
Symptomatic polycystic liver disease	35 (7.7)	32 (91.4)	1 (2.9)	19 (6.3)	14 (77.8)
Other liver tumors	26 (5.8)	23 (88.5)	10 (38.5)	21 (7.0)	12 (57.1)
Other	29 (6.4)	21 (72.4)	11 (37.9)	17 (5.7)	13 (76.5)
Refractory hydrothorax	21 (4.7)	18 (85.7)	7 (33.3)	12 (4.0)	7 (58.3)
Recurrent variceal bleed	23 (5.1)	17 (73.9)	6 (26.1)	17 (5.7)	12 (70.6)
Other non-variceal GI bleeding	22 (4.9)	19 (86.4)	3 (13.6)	13 (4.3)	7 (53.9)
PV or SMV thrombosis	15 (3.3)	11 (73.3)	7 (46.7)	8 (2.7)	3 (37.5)
Spontaneous bacterial peritonitis	6 (1.3)	6 (100.0)	1 (16.7)	5 (1.7)	3 (60.0)
Portopulmonary HTN or HPS	4 (0.9)	4 (100.0)	1 (25.0)	3 (1.0)	3 (100.0)

* P=0.61

[‡] Either asked for 15 points to specifically be eligible, to be able to get local, regional, or donation after cardiac death or extended-criteria donor organs. P=0.001; overall 148 (31.0%) of applications made specific mention of asking for 15 points to receive a score high enough to receive an organ. 85.7% vs. 78.9% (P=0.09) applications accepted when made specific mention (or not) of wanting exception points to receive organ

[‡] P=0.11

Table 5

Regional differences in applications for 15 exception points

Region	Total number applications	Number of applicants, (%)	Approval rate *
2	46 (10.2)	31 (10.3)	41 (89.1)
3	196 (43.4)	103 (34.2)	182 (92.9)
5	10 (2.2)	6 (2.0)	7 (70.0)
6	2 (0.4)	2 (0.7)	2 (100.0)
7	26 (5.8)	20 (6.6)	16 (61.5)
8	7 (1.6)	6 (2.0)	2 (28.6)
10	130 (28.8)	105 (34.9)	87 (66.9)
11	35 (7.7)	28 (9.3)	29 (82.3)
Total	452	301	366 (81.0)

*p<0.001 comparing regions

Table 6

Outcomes of applications for 15 exception points

	N (% of total applicants for 15 points)	Transplanted, N (%) [*]	Laboratory MELD at OLT, median (IQR) [†]	Allocation MELD at OLT [‡]	Removed for death or clinical deterioration ^{**}	Days from listing to death, median (IQR) ^{††}
All applications approved	223 (74.1)	158 (72.1)	11 (9–14)	15 (15–16)	19(8.5)	318 (126–1309)
Applications both accepted and rejected	15 (5.0)	5 (35.7)	10 (8–11)	15 (15–15)	2 (13.3)	386 (243–529)
All applications rejected	63 (20.9)	34(54.0)	12 (11–14)	15 (12–18)	9 (14.3)	889 (404–1544)

^{*} p=0.001 comparing three groups

[†] p=0.11 comparing three groups. 158/197 (80.2%) of patients had a laboratory MELD score less than 15 at the time of transplantation

[‡] p=0.19 comparing three groups

^{**} p=0.36 comparing three groups

^{††} p=0.41 comparing groups

MELD: Model for End-Stage Liver Disease

OLT: Orthotopic Liver Transplant

IQR: Interquartile Range