

OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Summary
October 20, 2015
Chicago, Illinois

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Discussions of the full committee on October 20, 2015 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov/>.

Committee Projects

1. National Liver Review Board

The MELD Enhancements and Exceptions Subcommittee presented its recommendations on the structure and operation of the National Liver Review Board (NLRB) to the full Committee. To increase the efficiency of the overall system, the Subcommittee also proposed automating the standardized MELD exceptions currently in policy and creating a way for candidates who miss an extension deadline to return to the auto approval track. The Subcommittee recommended that the Committee develop guidelines for the most common types of exceptions to ensure consistent review. Initial recommendations were well-received, and the Committee anticipates releasing a proposal for public comment in January 2016.

2. Liver Distribution Redesign Modeling (Redistricting of Regions)

The Committee requested analysis of multiple potential redistricting scenarios designed to address geographic disparities in access to deceased donor livers. Twenty-eight simulations were conducted, covering several redistricting schemes and multiple implementations of proximity circles. Results for these simulations were presented at the June 22, 2015 educational forum, which was attended in-person or online by over 400 people. Based on feedback received during the forum, Committee members asked for additional outputs to help determine the impacts of MELD/PELD exceptions on the various scenarios previously modeled.

The Committee reviewed the results of this additional analysis at its October 20, 2015 meeting in Chicago. This analysis confirmed several key findings from the previous analysis and added the following new results:

- For recipients without HCC exception points (about 77% of simulated transplants), the variation in allocation MELD/PELD at transplant is higher than in the overall all transplant group under the current liver distribution system.
- For recipients with no exception points (about 60% of simulated transplants) the variation in MELD/PELD at transplant was highest of all the examined subgroups.
- Overall, simulations indicate that variance in median MELD/PELD at transplant is projected to decrease under most of the redistricting scenarios, in the recipient population as a whole and in the subgroups with no HCC exception points and no exception points at all.
- Four-district scenarios offer the largest variance reduction, but 8-district scenarios also reduce variance compared with current policy.

Based on feedback from participants at the forum, the Committee also requested modeling of 500-mile concentric circle distribution based on the donor hospital location, with additional proximity points given to local candidates (at radii of 150 and 250 miles). The Committee anticipates reviewing the results of this modeling at its next in-person meeting in the spring of 2016.

Committee Projects Pending Implementation

3. Add Serum Sodium to the MELD Score

In June 2014, the Board approved a policy to modify the MELD score to include serum sodium concentration, which is an important predictor of survival among candidates for liver transplantation. Upon implementation of this policy in January 2016 (estimated), the MELD score will be recalculated to incorporate serum sodium for candidates with a MELD score greater than 11. Information necessary to calculate the revised score is already collected in UNetSM.

On July 20, 2015, the Executive Committee approved a clerical change to the policy for the purposes of implementation. Upon implementation, UNetSM will automatically recalculate a candidates' new MELD score. There will now be a 7-day grace period during implementation for those candidates whose scores would be moved from one recertification category to another, and may as a result require immediate recertification (i.e., the candidates would face an immediate downgrade of their MELD score). If a center has not recertified these candidates on the 8th day after implementation, the candidates will be downgraded to their previous lower MELD score as is currently done when certification expires. Information about implementation was recently shared with the community in a news article (<http://optn.transplant.hrsa.gov/news/meld-serum-sodium-policy-changes/>).

Implemented Committee Projects

4. Delay the Hepatocellular Carcinoma (HCC) Exception Score Assignment

On October 8, 2015, the OPTN implemented the policy to delay HCC exception score assignment. HCC applications are submitted as they have always been, but candidates are registered at their calculated MELD/PELD scores for the first three months (initial application) and for the first three month extension, as long as the candidate continues to meet the policy criteria. The Committee will now monitor the policy to evaluate whether it reduces the disparity in transplant rates and drop-out rates (defined as removal from the waiting list due to death or because too sick to transplant) for those with and without HCC exceptions.

The Committee discussed how UNetSM automatically provides a six month delay in the exception score assignment for candidates that meet policy criteria for automatic exception approval. However, in some circumstances a center has to submit an HCC exception application using the "Other Specify" dropdown to request HCC priority under the policy criteria. In these circumstances, centers submitting an initial exception application and subsequent 3-month extension should enter a **MELD score of 6 or a PELD score of -99** as the requested score. Entering the appropriate score will allow UNetSM to use the candidate's calculated MELD/PELD score during the initial 3-months and first extension period. While the candidate is listed at the calculated score, the score is subject to the MELD/PELD recertification schedule (the same requirement for candidates without an exception).

During the first few months post-implementation, Regional Review Board (RRB) members need to be aware of when an initial HCC request was submitted. If the initial HCC request was submitted before October 8, 2015, RRBs should approve a score of 25 on the first extension if the candidate meets the policy criteria. If the initial HCC request was submitted on or after October 8, 2015, RRBs should not approve requests for scores of 22 on the initial application, nor scores of 25 on the first extension, unless there are extenuating clinical circumstances, which should be stated clearly in the narrative text.

The Committee asked that these directions to assist centers and RRB members in complying with the new policy be shared in an emailed memo and an online article.

5. Cap the Hepatocellular Carcinoma (HCC) Score at 34

On October 8, 2015, the OPTN also implemented the policy to cap the HCC exception score at 34. Candidates with HCC exceptions automatically receive exception points every three months despite low drop-out rates. Increasingly, candidates with multiple HCC exception extensions were receiving regional offers under the “Share 35 Regional” policy. The Committee will now monitor the policy to evaluate whether capping the HCC exception score at 34 gives candidates with calculated MELD/PELD scores of 35 and higher a better opportunity to receive regional offers.

6. Regional Distribution of Livers for Critically Ill Candidates (Share 35)

The Committee continues to monitor several major adjustments to its liver and intestine allocation system for adult donor livers, implemented on June 18, 2013. These include:

- National sharing for candidates with MELD/PELD scores greater than 15
- Regional sharing for candidates with MELD/PELD scores of at least 35
- National sharing for liver-intestine candidates.

The Committee examined an analysis that compared the first two years after policy implementation to those of the pre-policy period. Key findings included the following:

- Overall regional sharing increased from 20.8% of deceased donor transplants to 32.0% of deceased donor transplants.
- The percentage of deceased donor transplants in the MELD/PELD 35+ category increased from 18.5% in the pre-era to 26.5% in the post-era.
- The percentage of liver transplants in the MELD/PELD 35+ category that were regionally shared increased from 18.9% to 50.0%.
- Overall, the median CIT was unchanged, despite the overall median distance increasing from 56 to 83 miles.
- The percent of livers recovered for transplant and not transplanted decreased slightly, from 10.3% to 9.5%.
- The percentage of donors from whom livers were not recovered decreased from 16.0% to 14.8%.
- No statistically significant differences in waiting list mortality rates or one-year patient survival rates were found.
- Candidates reaching a MELD/PELD score of 35 or higher had a greater transplant rate and a lower death rate in the post-policy era.

Upcoming Meeting

- November 20, 2015