

**OPTN/UNOS Liver and Intestinal Organ Transplantation Committee  
Report to the Board of Directors  
December 1-2, 2015  
Richmond, Virginia**

**Ryutaro Hirose, MD, Chair  
Julie Heimbach, MD, Vice Chair**

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*This report reflects the work of the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee from June through November 2015.*

**Action Items**

None

**Committee Projects**

1. National Liver Review Board

*Public Comment: January - March 2016 (Estimated)*

*Board Approval: June 2016 (Estimated)*

In November 2013, the Board directed the Committee to develop a plan for a National Review Board for MELD/PELD exceptions, with the goal of promoting consistent review of exception applications. The MELD Enhancements and Exceptions Subcommittee has investigated various concepts for implementing a national review board, and the Board most recently reaffirmed their support for this effort at its June 2015 meeting. In September 2015, the Vice Chair reconvened the MELD Enhancements and Exceptions Subcommittee to further develop the National Review Board proposal. On October 20, 2015, the Subcommittee presented its recommendations on the structure and operation of the National Liver Review Board to the full Committee. 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)

*Public Comment: TBD*

*Board Approval: TBD*

Despite continued improvements in liver allocation and distribution over the last 15 years, waitlist mortality remains high for candidates with higher MELD/PELD scores. Significant disparity exists between OPOs and regions with regard to the mean MELD/PELD score at transplant and waitlist mortality. The Committee has been examining ways to direct livers to those most in need. Simulation modeling suggests that optimized or fewer geographic districts would likely reduce the variation in MELD/PELD score at transplant and reduce waitlist deaths.

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

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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 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 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

*Public Comment:* March - June 2013

*Board Approval:* June 2014

*Implementation Date:* January 14, 2016 (Estimated)

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 14, 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 UNet<sup>SM</sup>.

On July 20, 2015, the Executive Committee approved a clerical change to the policy for the purposes of implementation. Upon implementation, UNet<sup>SM</sup> 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 8<sup>th</sup> day after implementation, the candidates will be downgraded to their previous lower MELD score as is currently done when certification expires.

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### 4. Reinstate the “No Appeal, No Withdrawal” Button for Denied MELD/PELD Exceptions

*Public Comment:* N/A

*Board Approval:* June 2009

*Implementation Date:* February 4, 2016 (Estimated)

If the Regional Review Board (RRB) does not approve an exception application within 21 days, current policy allows a transplant physician to register the candidate at the request MELD/PELD score following a conference call with the RRB. The case would then be automatically referred to the Liver and Intestinal Organ Transplantation Committee, and potentially the MPSC, for review. When this policy was first implemented in 2002, the physician could accomplish this by selecting the “no appeal/no withdrawal” button on the application after it was denied by the RRB. The button was inadvertently removed when a modification to the policy was subsequently implemented. In June 2009, the Board approved a proposal to reinstate the MELD/PELD exception “no appeal/no withdrawal” button. This is scheduled to be implemented on February 4, 2016.

### 5. Proposed Membership and Personnel Requirements for Intestine Transplant Centers

*Public Comment:* January - March 2015

*Board Approval:* June 2015

*Implementation Date:* TBD

In June 2015, the Board approved intestine program requirements. All transplant hospitals with intestine programs with a current status of “Active, Approval Not Required” will be required to apply for intestine program designation. Prior to implementation, the new application forms must be approved by the Office of Management and Budget (OMB). This approval process will begin in November 2015.

## Implemented Committee Projects

### 6. Develop Materials to Educate RRB Members and Promote Consistent Review of Exceptions

*Public Comment:* N/A

*Board Consideration:* N/A

*Implementation Date:* September 10, 2015

As part of ongoing efforts to standardize the exception review process, the Committee held an educational webinar for all liver RRB members on September 10, 2015. During this webinar, the Committee Chair shared the purpose of the RRB, reviewed member roles and responsibilities, and gave guidance on what to look for when reviewing exception applications.

A recording of this webinar is available on the Review Board page in Waitlist under RRB Help Documentation. Liver RRB members can log into UNet<sup>SM</sup> at <https://portal.unos.org> and select the “Regional Review Board” icon to access the page.

### 7. Delay the Hepatocellular Carcinoma (HCC) Exception Score Assignment

*Public Comment:* March - June 2014

*Board Approval:* November 2014

*Implementation Date:* October 8, 2015

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.

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

*Public Comment:* [March - June 2013](#)

*Board Approval:* [November 2014](#)

*Implementation Date:* October 8, 2015

On October 8, 2015, the OPTN 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 (defined above). 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.

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

*Public Comment:* [September 2011 - January 2012](#)

*Board Approval:* [June 2012](#)

*Implementation Date:* June 18, 2013

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.

During its most recent in-person meeting on October 20, 2015, 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%.

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- 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.

### **Review of Public Comment Proposals**

The Committee reviewed two of the proposals released for public comment from August – October 2015.

#### **10. Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws**

After a presentation of the proposal, the Chair expressed that this proposal has been well-developed over several years with a lot of input from stakeholders and fulfills the need for pediatric membership requirements. Although the proposed case volume requirements appear arbitrary, they were developed through clinical consensus. He believes the requirements are reasonable, citing the involvement and endorsement of the American Society of Transplant Surgeons (ASTS). These sentiments were echoed by several members.

Others had reservations about requiring transplant programs to have a pediatric component in order to perform transplants in teenagers. Members requested evidence that adolescents transplanted at pediatric programs have better post-transplant outcomes. They also wanted to know if teenagers comprised the majority of the estimated 4% of pediatric transplants performed in the past five years at programs that did not meet the proposed criteria. Members also expressed support for an emergency exception to the pediatric requirements.

#### **11. Simultaneous Liver Kidney (SLK) Allocation Policy**

After a presentation, the Committee voted unanimously to support the proposal with the amendments proposed by the leadership from both the Liver and Kidney Committees (13-Yes, 0-No, 0-Abstentions). These amendments include:

- A requirement that local SLK candidates meet the kidney medical eligibility criteria only and that regional SLK priority be contingent on both medical eligibility criteria and Liver “Share 35” priority.
- If an OPO chooses to allocate the kidney as an SLK combination, the OPO must offer to eligible local and regional SLK candidates before offering the kidney alternatively.
- The medical eligibility criteria does not apply to pediatric SLK candidates.

While there is not consensus about national allocation, out-of-region SLK offers should not be expressly prohibited, as is implied by the proposed language.

Several members were in favor that a program should be able to register a candidate within 30 days post-liver transplant, instead of the proposed minimum of 60 days post-transplant. They believe surgeons can make a determination about whether a candidate will recover renal function within a 30-day timeframe, especially if the candidate showed signs of renal failure prior to transplant.

### **Other Committee Work**

None

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### **Meeting Summaries**

The committee held meetings on the following dates:

- June 12, 2015
- June 23, 2015
- July 31, 2015
- August 24, 2015
- September 18, 2015
- October 20, 2015

Meetings summaries for this Committee are available on the OPTN website at:  
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=25>.