

**Liver and Intestinal Organ Transplantation Committee
Conference Call
December 13, 2010 3pm EST
Interim Report**

1. Report from the Board of Directors Meeting, November 2010. The Committee was informed that the Region 2 and OneLegacy AASs were approved by Board, and that the Board also directed the Committee to pursue a committee-sponsored AAS for split livers. The request for an AAS by three OPOs in Ohio was not approved. The Committee's request to extend Region 8 AAS until June 2011 was tabled by the Board.

2. HCC Imaging Proposal. The Committee reviewed the proposal to incorporate new imaging criteria into policy 3.6.4.4 (Liver Candidates with Hepatocellular Carcinoma (HCC)). The latest draft of the proposal had been updated to reflect the classifications used in the published paper from the HCC consensus conference held in November 2008. The entire policy has been reorganized so that it will be easier to follow. Several aspects of the proposed policy were discussed:
 - The policy would no longer allow several sub-centimeter tumors to count towards T2 staging, and there would be more requirements for smaller lesions.
 - The proposed policy includes the following: "Any imaging examination performed for the purpose of obtaining or updating priority points on the transplant waitlist *should* meet minimum technical and imaging protocol requirements for CT and MRI listed in Table 4 and Table 5." This says "should" because based on the survey, it is estimated that almost all centers already meet these requirements, but for DEQ staff to monitor compliance with this would be very difficult.
 - Images must be interpreted at the transplant center. An earlier version of the proposals would have allowed images to be read by a multidisciplinary team such as a tumor board, but the subcommittee felt it is important to be more stringent on this point.

The Committee reviewed proposed OPTN classifications 5A, 5A-G, 5-B, and 5T. These fit into a larger imaging classification scheme developed by radiologists for liver imaging (LIRAD). These criteria were developed by radiologists, and radiologists at 45 centers were surveyed to develop consensus. The Committee suggested an additional classification for those larger than Stage T2 (e.g., Class 5X). The Committee also suggested that the requirement for documentation to be clarified to state that, "Documentation of the radiologic characteristics of each OPTN class 5 nodule (for an example, see Tables 7A-C) must be kept on file at the transplant center " and that Tables 7A-C should contain a signature block for the radiologist.

The Committee approved the proposal to be circulated for public comment by a vote of 17 in favor, 1 opposed, and no abstentions.

3. Proposal for Broader Distribution of Adult Livers for Liver-Intestine Candidates. The Committee reviewed the proposal for broader distribution to candidates awaiting a combined liver-intestine transplant. Death rates for these candidates are nearly three times higher than for those waiting for a liver alone. The Committee had requested an analysis of the death rates from small-statured candidates, as these compete for the same donor pool. The analysis showed that, while small-statured liver-alone candidates do have an increased risk of death, it was much lower than for liver-intestine candidates. The subcommittee suggested the following modification to the Adult Donor Liver Allocation Algorithm:

Combined Local and Regional

1. Status 1A candidates in descending point order
2. Status 1B candidates in descending point order.

Local

3. Candidates with MELD/PELD Scores ≥ 15 29 in descending order of mortality risk scores (probability of candidate death)

National

4. Liver-Intestine Candidates in descending order of mortality risk scores (probability of candidate death)

Local

5. Candidates with MELD/PELD Scores 15-28 in descending order of mortality risk scores (probability of candidate death)

Regional

6. 4 Candidates with MELD/PELD Scores ≥ 15 in descending order of mortality risk scores (probability of candidate death)

Local

7. 5 Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

Regional

8. 6 Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

National

9. 7- Status 1A candidates in descending point order

10. 8- Status 1B candidates in descending point order

11. 9- All other candidates in descending order of mortality risk scores (probability of candidate death)

The subcommittee had also discussed changing to the MELD score assigned to these candidates to a minimum MELD score of 20, or the calculated MELD score plus 5 additional points. The current increase assigned to these candidates already results in a minimum score of 20. The latest SRTR data show a 5-point mortality differential between liver-intestine and liver-alone candidates. Further, a recent OPTN analysis showed that the MELD score that represented a comparable death rate for these candidates would be approximately 22. This proposal would place the candidates with lower scores than the HCC exceptions, and would allow patients with MELD scores higher than 24 to compete for local donors. The national share is intended to dilute the impact in any one region.

The Committee felt that it might be confusing to change both the distribution and the allocation components at the same time, and agreed to go forward with the distribution changes only at this time, by a vote of 14 in favor, 0 opposed, 0 abstentions.

4. Committee sponsored AAS. As requested by the Board, the Committee voted to support a committee-sponsored AAS for split liver allocation based on the Region 2 and OneLegacy proposals, by a vote of 14 in favor, 0 opposed, 0 abstentions.
5. Items Circulated for Public Comment, October 1 2010 - February 5, 2011. The Committee reviewed several items with potential impact on liver transplantation.
 - A. Proposal to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Reporting Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy. The Committee voted to support this by a vote of 14 in favor, 0 opposed, 0 abstentions.
 - B. Proposal to include Qualifications for Director of Liver Transplant Anesthesia in the Bylaws. Committee members asked whether (a) this position would be considered 'key personnel,' and if there would be some pathway if the Director of Liver Anesthesia left a transplant program and (b) the requirements for the number of transplants performed would adversely impact pediatric programs. A UNOS staff liaison to the MPSC noted that the only parts of the proposed by-law that would be mandatory are the first two requirements: the center shall designate a Director of Liver Transplant Anesthesia who must be board certified. Everything else in the proposal is a recommendation only. It was noted that the Pediatric Committee was in support of this proposal, as these are a very minimum level of qualifications. The Committee voted to support this by a vote of 14 in favor, 0 opposed, 0 abstentions.
 - C. Safety Proposal: Prohibiting Storage of Hepatitis C Antibody Positive and Hepatitis B Surface Antigen Positive Extra Vessels. The Committee had significant concerns about this proposal, in that it could create a shortage of vessels, and could potentially preclude a center from storing vessels for someone who has hepatitis C from a hepatitis C positive donor. Committee members felt that there could be other options, such as prohibiting vessel between institutions or patients, or requiring a, "time-out" when using vessels. Others suggested that the committee wait and see whether the new donor labels help such situations. It was noted, however, that almost all of the errors that occur are labeling errors. The Committee did not support this proposal by a vote of 2 in favor, 12 opposed, and no abstentions.
6. Data request for MELD exceptions. The Committee asks for data related to the standard MELD/PELD exceptions implemented in March 2010. The request is as follows:

- Compare the number of cases, waiting list outcomes, and post-transplant outcomes for the candidates with the new standardized exception criteria to that of candidates with HCC and standard MELD candidates with no exceptions.
 - Include the number of exceptional case requests by region and the number of cases submitted that do not meet criteria and the number of cases submitted where the requested MELD/PELD score is higher than the assigned policy.
7. Status 1 Case Not Meeting Criteria. The Committee reviewed additional information that was provided for a case reviewed in October. In June 2010, the center had listed a patient as status 1A who did not meet criteria, and the subcommittee found the listing to be inappropriate, with most indicating that the patient should have been listed with a MELD of 40. The case did not meet criteria because the patient had hepatic artery thrombosis (HAT) but the AST was less than 5000 (the reported value was 166). An appeal was denied by the subcommittee. The center had two prior status 1A cases not meeting criteria in the prior year. The Committee voted to send these cases to the MPSC for review by a vote of 14 in favor, 1 opposed, 0 abstentions.
8. Approval of Cholangiocarcinoma (CCA) Protocol. The Committee agreed to approve an amended protocol for a center that had modified a previously–approved protocol, as recommended by the Subcommittee.

**Committee Participation
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W. Kenneth Washburn, MD	Chair	X
Kim Olthoff, MD	Vice Chair	X
Michael Curry, MD	Regional Rep. Region 1	X
Stephen Dunn, MD	Regional Rep. Region 2	X
Brendan McGuire, MD	Regional Rep. Region 3	X
Goran Klintmalm, MD, PhD	Regional Rep. Region 4	X
Ryutaro Hirose, MD	Regional Rep. Region 5	X
Jorge D. Reyes, MD	Regional Rep. Region 6	X
Anthony D'Alessandro, MD	Regional Rep. Region 7	
Harvey Solomon, MD	Regional Rep. Region 8	
Lewis Teperman, MD	Regional Rep. Region 9	X
John Fung, MD, PhD	Regional Rep. Region 10	X
Michael Marvin, MD	Regional Rep. Region 11	X
Scott Biggins, MD	At Large	X
Julie Heimbach, MD	At Large	X
Heung Bae Kim, MD	At Large	X
Timothy McCashland, MD	At Large	
Kenyon Murphy, JD	At Large	X
John Roberts, MD	At Large	X
Debra Sudan, MD	At Large	
Kim Brown, MD	At Large	
Kareen Abu-Elmagd, MD	At Large	X
Michael Charlton, MD	At Large	
James Trotter, MD	At Large	
Thomas Mone	At Large	X
James Eason, MD	At Large	X
Monica Lin, PhD	Ex Officio, HRSA	X
James Bowman, MD	Ex Officio, HRSA	X
Jon Snyder, PhD, MS	SRTR Representative, MMRF	X
Yi Peng, MS	SRTR Representative, MMRF	X
David Zaun, MS	SRTR Representative, MMRF	X
W. Ray Kim, MD	SRTR Representative, MMRF	X
Sally Aungier	UNOS, Liaison to MPSC	X
Erick Edwards, PhD	UNOS, Assistant Director, Research	X
Ann Harper	UNOS, Policy Analyst	X
Brian Shepard	UNOS, Director of Policy	X
Chad Waller, MS	UNOS, Policy Analyst	X
Jory Parker	UNOS, Business Analyst	X