

**Interim Report of the
OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
November 18, 2009**

1. Review of Actions Taken During the November 16-17, 2009 Board of Directors Meeting. The Board approved the Committee's revisions to Policy 3.6.4.5 (Liver Candidates with Exceptional Cases), but did not approve the request to program the MELD/PELD exception applications in UNetSM similar to the auto-approval process for HCC exception applications. The Board approved the Committee's proposed interim solution to handle these cases without programming, as outlined in the revised Regional Review Board (RRB) Guidelines.
2. Center MELD/PELD Exception Appeal to Liver Committee. The Committee discussed a request from a center to review an exceptional case MELD score application that had been denied by the RRB. After hearing the presentation from the center's representative, the Committee decided to uphold the actions of the RRB (19 in favor, 0 opposed, 3 abstentions).
3. Review of SRTR Modeling Efforts. The SRTR provided an update on its transplant survival benefit models, including new modeling for "Share positive benefit," which is based on the Share 15 concept but replaces the MELD/PELD 15 threshold with a benefit score of greater than zero. Committee members were concerned about the complexity of the formula from which the benefit scores are derived and the applicability of the benefit score in a clinical setting. The Committee asked that the SRTR develop a simplified model, perhaps using the top five most significant factors in the current model. The Committee also asked for modeling of the "Share 15 national" concept, which would extend the current Share 15 policy to all candidates nationally with a MELD/PELD score of 15 or higher before any patients with lower MELD/PELD scores. The Committee would like the SRTR to investigate other thresholds for the use of concentric circles as the initial distribution unit, perhaps starting with a 250-mile radius. The Committee discussed other concepts for constructing distribution units, such as population density or some percentage of the waiting list.
4. INR and MELD score Variation. James Trotter, MD, summarized problems related to the use of the international normalized ratio (INR) as a determinant in the MELD score. These are related to the effect of significant inter-laboratory variability of the INR and the MELD score. Variability can undermine the fundamental purpose of the MELD score to provide an objective, simple and reliable means to prioritize patients for liver transplantation. The Committee did not take any action on this issue at this time.
5. MELD Exceptions Subcommittee. The MELD Exceptions Subcommittee has created templates that centers would use to enter the required information for the newly approved standardized MELD/PELD exceptions. These templates will be circulated to the transplant programs, and center personnel will have to fill in the requested information and paste it into the narrative field of the exception application. The Committee would like to pursue other automated processes for centers to submit this information to UNOS. Members of the Committee also agreed to review the protocols

required for centers to submit cholangiocarcinoma exceptions; five centers have submitted protocols to date.

The Committee also discussed an issue that had been brought to its attention during a conference call in October. There is an inconsistency in the way MELD/PELD scores are assigned to exceptions for candidates with HCC meeting the policy criteria versus other exceptions (including HCC not meeting criteria). Candidates with standard HCC exceptions are automatically assigned a MELD score of 28 upon the second extension, which is the correct score for a 10% increase in mortality risk. However, candidates with other exceptions receive a score of 27. There is a “work-around” that allows these candidates to be assigned to correct score. The Committee agreed that both types should receive the same scores (Committee vote: 22 in favor, 0 opposed, 0 abstentions). The Committee also unanimously approved a change to the HCC policy that would make the text of the policy language consistent with the Milan criteria.

The Committee reviewed two exceptional cases that were not approved by the RRB within 21 days, and were transplanted at the requested score. In one case, the Committee suggested that the center be sent a letter reminding them to provide appropriate documentation in its applications, and that future cases could be referred to the Membership and Professional Standards Committee (MPSC). No action was taken on the other case.

6. Intestine issues Subcommittee. The Committee discussed a proposal to give more priority to adult candidates awaiting a combined liver-intestine transplant. Recent data indicate that these candidates have twice the mortality rate of adult liver-alone candidates. Committee members discussed whether these candidates should receive a higher MELD/PELD score than they are currently assigned, or whether broader access to organs (e.g., a national share) is necessary. The subcommittee will continue to work on a proposal for the Committee to circulate for public comment. The subcommittee is also continuing its work on surgeon and physician criteria for intestine programs, and has received feedback from the MPSC on its draft proposal.
7. Guidelines for Director of Liver Transplant Anesthesia. The Committee reviewed the Guidelines for Director of Liver Transplant Anesthesia developed by the American Society of Anesthesiologists Committee on Transplant Anesthesia. These had been presented to the Committee in draft form in July. The Committee voted that the guidelines should be forwarded to the MPSC by a vote of 21 in favor, 1 opposed, and 0 abstentions.
8. Status 1 Review Subcommittee. The Committee discussed Status 1A and 1B cases that did not meet the criteria in policy, and were therefore reviewed retrospectively by the Status 1 Review Subcommittee. Three cases will be forwarded to the MPSC for further action.
9. Joint Liver-Pediatric Subcommittee. The Subcommittee is recommending that policy 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma) should be amended to remove the requirement that these candidates must spend 30 days listed with a MELD/PELD score of 30 prior to being eligible for listing as a Status 1B. The Committee reviewed data showing the number and percentage of candidates transplanted as a Status 1B versus a MELD/PELD score of 30, and the

number of days spent in each status/score prior to receiving a transplant. The Committee unanimously agreed that the requirement should be removed. The Committee also discussed proposals for increasing the number of split liver transplants; the subcommittee will continue to work towards a proposal.

10. Region 2 Split Liver Alternative Allocation System (AAS). Region 2 is requesting an AAS that would allow a center that accepts a liver for a candidate, and is willing to split the liver, to transplant the remaining segment into another candidate on its waiting list. The Committee approved this proposal for review by the Policy Oversight Committee and submission for public comment by a vote of 19 in favor, 1 opposed, and 1 abstention.
11. Living Donor Liver Transplantation Requirements. A joint subcommittee of the MPSC and the Liver and Living Donor Committees is proposing changes to the requirements for living donor liver transplant programs. The Committee was in unanimous support of the proposed changes.
12. Proposal to Improve the Variance Appeal Process Affected Policy: 3.4 (Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation). The Committee reviewed this proposal from the Policy Oversight Committee but had no comments at this time.

**Committee Attendance at the
November 18, 2009 Committee Meeting
Chicago, IL**

NAME	COMMITTEE POSITION	In Attendance
W. Kenneth Washburn, M.D.	Chair	X
Kim Olthoff, M.D.	Vice Chair	
Michael Curry, M.D.	Regional Rep.	X
Stephen Dunn, M.D.	Regional Rep.	X
Nigel Girgrah, M.D., Ph.D.	Regional Rep.	X
Goran Klintmalm, M.D., Ph.D.	Regional Rep.	X
Scott Biggins, M.D.	Regional Rep.	X
John Ham, M.D.	Regional Rep.	X
Anthony D'Alessandro, M.D.	Regional Rep.	by telephone
Harvey Solomon, M.D.	Regional Rep.	X
Thomas Schiano M.D.	Regional Rep.	X
Shawn Pelletier, M.D.	Regional Rep.	X
James Eason, M.D.	Regional Rep.	X
Maureen Burke-Davis, RN, NP-C, CCTC	At Large	X
Patricia Carroll PA-C, CPTC	At Large	
Julie Heimbach, M.D.	At Large	X
Heung Bae Kim, M.D.	At Large	X
Timothy McCashland, M.D.	At Large	X
Lisa McMurdo, RN, MPH	At Large	X
Kenyon Murphy	At Large	X
John Roberts, M.D.	At Large	X
Debra Sudan, M.D.	At Large	X
Kerri Wahl, M.D.	At Large	X
Elizabeth Pomfret, M.D., Ph.D.	Ex Officio	X
Bernard Kozlovsky, M.D., MS	HRSA	X
Monica Lin, Ph.D.	HRSA	X
Mary Guidinger, MS	SRTR Liaison	X
John Magee, M.D.	SRTR Liaison	X
Douglas Schaubel, Ph.D.	SRTR Liaison	X
Ann Harper	Committee Liaison	X
Erick Edwards, Ph.D.	Research Support Staff	X
Manny Carwile	IT Support Staff	X