

**OPTN/UNOS Liver and Intestinal Organ Transplantation Committee**  
**July 23, 2012**  
**Conference Call**  
**INTERIM REPORT**

1. Introductions /Welcome New Committee Members. At the start of the call, Kim Olthoff, MD, Committee Chair, introduced the new members of the Committee.
2. Brief Board Meeting Update. Dr. Olthoff informed the Committee that the Share 15 and Share 35 proposals were approved by the Board of Directors in June 2012. The Board also approved the liver biopsy resources developed by the former Organ Availability Committee.
3. Regional Review Board Primer. The Committee received a brief introduction to Regional Review Board (RRB) processes and the duties of the regional representatives as RRB chairs. The RRBs approve requests for MELD/PELD exceptions. The criteria for exceptions are described in several policies: 3.6.4.5 (Liver Candidates with Exceptional Cases) and subsections 3.6.5.1-3.6.5.6, 3.6.4.3 (Pediatric Liver Transplant Candidates with Metabolic Diseases), 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)), and 3.6.4.1 (Adult Candidate Status) for candidates with hepatic artery thrombosis. The RRBs are also governed by the RRB Operational Guidelines; this document includes the rules for transplant center representation and alternate voters, as well as the responsibilities of RRB chairs and members in terms of voting procedures and timeliness of voting. The guidelines were last approved by Board in 2009; however, some modifications to the guidelines will be submitted to the Executive Committee in August, 2012, to incorporate current practice for Chrysalis programming.

Per the policies and the guidelines, applications for “standard” MELD exceptions (those outlined in Policies 3.6.4.5.1-3.6.4.5.5) are reviewed by the RRB chair. The criteria and scores are outlined in policy, and centers are expected to use the templates provided to them to ensure that the required information is included in the clinical narrative. This is an interim ‘non-programming’ solution until these can be programmed as automatic exceptions in UNet<sup>SM</sup>. The RRB Chair is expected to approve the application if the criteria are met. Applications are sent to entire RRB if the criteria are not met. All other exceptions are sent to the RRBs for a vote. Several regions have developed agreements for approval of specific diagnoses, which is acceptable per the policy.

Standard HCC applications (those that meet all criteria and are automatically approved by UNet) are assigned initial and extension scores on a percentage mortality risk (15%, 25%, 35%, etc) and the assigned scores are fixed at each extension (22, 25, 28, 29, etc). All other exception applications, including those HCC applications that meet criteria but have missed a deadline, begin with a requested score, and the percentage mortality is “back-calculated” with each extension. This calculation results in different score for second extension (27 versus 28), so centers must ask the RRB for a score of 28 in order to stay on the same track as standard HCCs. To change this would require complete reprogramming of exceptions. The Committee reviewed an example of the calculation that leads to this difference in scores. It is important for RRB members to understand this issue, as it has lead to many requests to the RRBs.

The Committee discussed other areas of concern that have been expressed related to MELD/PELD exceptions, in particular, the very high number of non-standard MELD exceptions. This will be

reviewed by the MELD enhancement working group to see if there are ways to standardize some of the differences in exception practices across regions. There have been several published studies on the lower “dropout rates” for candidates with HCC versus those without HCC exceptions, which suggest that these candidate are being awarded too much priority relative to other candidates. The HCC subcommittee is reviewing several possible solutions to this issue, and may have a proposal for public comment within the next six months.

The Committee reviewed data on the number of exceptions by diagnosis and Region.

The Committee was reminded that Status 1 listings that do not meet criteria are reviewed by the Status 1 Review Subcommittee on behalf of the Liver/Intestine Committee. These are retrospective reviews, although members may request a prospective review.

4. RRB Streamlining Project. The Committee received a brief overview of this project, which began with a request from then UNOS President, John Lake, MD in March 2012. As a result of two projects that UNOS staff had been working on in parallel, the Policy Rewrite Project and the Chrysalis programming project, it became clear that making the Regional Review Boards more consistent in their processes could save substantial programming costs, as well as make the policies clearer and easier for the public, practitioners, and staff to understand. At Dr. Lake’s request, a subcommittee was formed consisting of representatives from the Liver and Intestinal Organ Transplantation and Thoracic Organ Transplantation Committees. The subcommittee has met several times by conference call and has proposed ideas for change to the system. In July 2012, the subcommittee was asked to limit the scope for the time being in order to focus on some decisions that are required to allow the Chrysalis programming to proceed. These include:
  - How and when to count alternate votes
  - Voting: defining tie breakers, quorum, and majority
  - The effect of a negative vote by a review board
  - Extensions of exceptions

Other issues can be pursued later. For the Liver RRBs, these changes will be limited to the RRB Operational Guidelines, essentially putting in writing what is already being done in practice. The policies should be unchanged. One slight change will be made to the interpretation of the “21-Day Rule.” Policy states that “If approval is not given within twenty-one days, the candidate’s transplant physician may list the candidate at the higher MELD or PELD score, subject to automatic referral to the Liver and Intestinal Organ Transplantation Committee for review. Currently the system defaults to grant the score; in Chrysalis, center will have to use the override button.

The Executive Committee will discuss the proposed changes in late August.

5. Policy Rewrite. The Committee was asked to review the proposed plain language rewrite of the Liver and Intestinal allocation policies, and provide feedback by August 31, 2012.
6. Subcommittees/Working Groups. The Committee reviewed the subcommittees and working groups and their charges. Committee members were asked to identify which of the following subcommittees and/or working groups they like to serve on:
  - HCC Working Group

- Liver Utilization Working Group
- MELD Exceptions/Enhancements Working Group
- PELD Working Group
- Joint Pediatric-Liver Subcommittee
- Intestine Working Group

**Attendance, July 23, 2012**

Kim Olthoff, MD	Chair	X
David C. Mulligan, MD	Vice Chair	
Adel Bozorgzadeh, MD	Regional Rep. Region 1	X
Andrew Cameron, MD	Regional Rep. Region 2	
George Loss, MD	Regional Rep. Region 3	X
Mark R. Ghobrial, MD, PhD	Regional Rep. Region 4	
Johnny C. Hong, MD	Regional Rep. Region 5	X
Susan Orloff, MD	Regional Rep. Region 6	X
David C. Cronin, II, MD, PhD	Regional Rep. Region 7	
Michael D. Voigt, MB, ChB	Regional Rep. Region 8	
Milan Kinkhabwala, MD	Regional Rep. Region 9	
Atsushi Yoshida, MD	Regional Rep. Region 10	
Kenneth Chavin, MD	Regional Rep. Region 11	X
Fredric D. Gordon, MD	At Large	X
Burnett (Beau) S. Kelly Jr., MD	At Large	X
Leona Kim-Schluger, MD	At Large	X
Nancy Knudsen, MD	At Large	
Manuel Rodriguez-Davalos, MD	At Large	X
Kirti Shetty, MD	At Large	
Mike Wachs, MD	At Large	X
Simon P. Horslen, MB, ChB	At Large	X
Thomas Starr	At Large	X
Fredric G. Regenstein, MD	At Large	
Srinath Chinnakotla, MD, MCh	At Large	
Ryutaro Hirose, MD	At Large	X
Ken Murphy, JD	Board Liaison	X
Ba Lin, PhD	HRSA, <i>ex officio</i>	X
Monica Lin, PhD	HRSA, <i>ex officio</i>	X
Peter Stock, MD	SRTR	X
Ajay Israni, MD	SRTR	X
Kimberly Neiman, MS	SRTR	X
Ann Harper	UNOS, Committee Liaison	X
Erick Edwards, PhD	UNOS Research Support Staff	X
Cheryl Hall	UNOS, Business Analyst	X
Susan Duerksen, RN, MSN	UNOS, Site Surveyor	X
James Alcorn, JD	UNOS, Policy Director	X
Liz Robbins, JD	UNOS, Liaison, Thoracic Committee	X
Aaron McKoy	UNOS, RRB Supervisor	X