

**OPTN/UNOS Liver and Intestinal Organ Transplantation Committee**  
**October 20, 2010, Chicago, IL**  
**Interim Report**

1. Introductions and Orientation. The Committee received orientations regarding several topics related to the Committee's work, including:
  - OPTN: Structure and Committees/Subcommittees;
  - Committee Charge and Annual Goals;
  - Effective Use of Data by OPTN Committees; and
  - Policy Development.
  
2. Next Steps on Liver Distribution. The Committee reviewed the recent history of policy development towards changes to the distribution of livers, including the RFI distributed in December 2009 and the Forum held in April 2010. Feedback from these mechanisms was reviewed by the Committee to determine the next steps. Several concepts emerged as feasible changes to the distribution system:
  - Share 15 national;
  - Tiered regional sharing;
  - Risk-equivalent threshold; and
  - Better utilization/expedited placement of deceased donor livers.

The Committee reviewed a draft document that outlines these concepts. This is intended to be a high-level discussion/overview of several concepts that represent step-wise improvements. Feedback from the concept paper will help the Committee to understand the community's current willingness for change. If a policy proposal is subsequently developed and circulated for public comment, it would include greater detail in terms of the impacts of any proposed changes. Committee members asked that the data in Figures 1-4 be updated through 2009. There were also several requests to rename the 'risk-equivalent threshold,' which is probably not an accurate name for the concept being described. The Committee unanimously approved a motion to proceed with the concept paper.

3. Review of SRTR Analytic Data Requests. The Committee reviewed the status of analytic requests made of the SRTR over the last year. The Committee also reviewed a new analysis of waiting list deaths by MELD/PELD score for several of the policies modeled using LSAM. Earlier data provided to the Committee showed only the total number of deaths by MELD/PELD category, without providing the denominator. A large number of deaths are in patients with lower MELD scores, but a large proportion of patients waiting are also listed with low MELD scores. The Committee felt that showing the percentage of deaths within ranges of MELD score would provide a better understanding of the death rates and risk of death by MELD/PELD category. The categories were based on candidates' MELD/PELD score at listing. This was acknowledged as a limitation, as candidates MELD scores change while on the waiting list.

The Committee also discussed the potential for a policy change to alter center behavior, such that the outcome of the policy change is not as predicted. For example, the modeling for the Share 15 Regional policy predicted that a larger percentage of livers would be transplanted into patients with MELD scores less than 15 than was the case after implementation. The hypothesis is that centers changed their organ acceptance behavior once Share 15 was implemented. In general, LSAM was designed to predict what would happen with a policy change, all else being equal. LSAM can incorporate predicted changes in behavior; however, the Committee must first agree upon what changes should be modeled and what the magnitude of the changes might be. The Committee was reminded that the SRTR uses the 5-step policy development checklist created by HRSA to build and monitor its models.

4. Hepatocellular Carcinoma (HCC) Subcommittee Report. The Committee reviewed the results of its survey of proposed HCC imaging criteria, which were based on the recommendations from the HCC Consensus Conference held on 2008. Proposed changes to the policy include:

- A requirement that studies must meet minimum technical and imaging protocol requirements (table 4 and 5);
- A requirement that the study must be interpreted by the transplant center radiologist or a multidisciplinary team at the center who would document images meet criteria;
- A more precise classification system for HCC lesions (Class 0-5). Only class 5A and 5D (5A lesions treated by various modalities) lesions would be eligible for exception (table 6); and
- Nodules <1cm indeterminate and not able to be considered.

The Committee received 77 responses to the imaging survey. Eighty-six percent supported a change that would more clearly define the imaging characteristics of HCC, and 92% supported a policy requiring images used for documentation of HCC to be performed at the transplant center or be reviewed by a multi-disciplinary team at the transplant center. Ninety percent of respondents reported that the imaging specifications are similar to what is currently being used at their transplant centers. The Subcommittee will review the individual comments submitted with the survey prior to making a final proposal.

The Subcommittee will also discuss policy monitoring and auditing with Department of Evaluation and Quality (DEQ) staff. One issue of concern is the requirement for scans to be performed at the transplant center, or reviewed by a multidisciplinary team (or tumor board) at the center. It may be difficult to ascertain whether scans performed outside the transplant center meet the criteria in the policy, and repeat scans at the center may not be reimbursed by insurance companies. The official review at the transplant center would serve to certify whether the HCC meets criteria or not. Committee members were concerned about how auditors would view the various pieces on information. Also, centers will often list a patient based on an outside scan, and then perform their own scans at the time of the HCC exception extension. Some members noted that, if the policies require repeat scans, the insurance companies may actually change their practice and reimburse for

them. The Committee can monitor this practice if the policy is implemented. The Subcommittee will finalize the language, and the Committee will vote on the proposal during its next call.

#### *Post-Transplant Pathology Reports*

The Committee's request for a standardized on-line pathology form will be submitted to the Board in November 2010. These will be required for all patients transplanted with a MELD/PELD exception for HCC. The Committee discussed whether pathology reports should be required for non-standard HCC exceptions, such as those outside the Milan criteria, or those that do not meet criteria for administrative reasons, such as a missed extension. Some centers submit exceptions for "other, specify" (non-HCC), but indicate HCC in either the diagnosis field or the clinical narrative.

The primary goal of requiring the pathology forms is to monitor compliance with the exception policy. The Committee felt that these forms should be required for any patient with an HCC exception at transplant. The Committee also decided that the pathology reports should be submitted within 60 days post-transplant; this will be incorporated into Policy 7 (Data Submission Requirements).

#### *Priority for HCC Allocation*

The Committee discussed the current priority given to candidates with HCC. Recently published data indicate that there is a higher rate of waiting list "drop-out" for candidates without HCC exceptions than those with HCC exceptions. This suggests that candidates with HCC exceptions are being given too much priority relative to other patients. The HCC exception scores appear to be driving the scores at transplant for all other candidates. The scores given to HCC patients have been decreased several times since the MELD/PELD implementation in 2002. The Committee discussed two possible solutions to address this issue. The first is to develop a continuous allocation score that would rank candidates with HCC among the non-HCC candidates on the waiting list, based on the MELD score, tumor size, AFP, and tumor growth. This was recommended in the HCC Consensus Conference report, and incorporates factors known to influence wait list survival. However, there are still questions regarding how to weight these factors, as well as how to handle patients treated with ablative therapy (with respect to tumor growth), and the possible impact on post transplant survival.

Another option would be to lengthen the interval at which HCC candidates receive extension upgrades beyond the current 90 days. The interval could potentially be different for each region. This would be less complicated and represents a more moderate change. However, this is a different approach from what was developed by consensus, and would need to be modeled to determine the impact.

Some members noted that candidates with HCC may not be advantaged relative to other patients in certain specific regions. Areas of the country where candidates with HCC wait longer are reporting higher rates of HCC recurrence. Other members stated that candidates without HCC exceptions

must have higher MELD scores than the HCC patients in order to get offers in their areas, highlighting disparities resulting from regional boundaries. Several Committee members felt that additional data on recurrence, plus analysis of data from the on-line pathology reports, will be necessary in order to make another change to the policy. The Subcommittee will determine what additional data is required to move forward.

5. Liver Utilization Working Group Update. The Liver Utilization Working Group was formed following the Forum held in April 2010. The working group was asked to: (1) Evaluate and assess the magnitude of expedited liver placements; and (2) formulate a transparent process for expedited liver placement that will enhance utilization and decrease discards. The Subcommittee had met once by conference call, and requested several analyses related to organ offer refusals and discards. The Committee reviewed a preliminary analysis of the 375 livers that were transplanted outside the region of the recovering OPO during 2009. These data were stratified by the state of the recovering OPO and the transplant center, as well as by the MELD score of the recipients. The working group also requested that the data be separated by adult versus pediatric donors, as well as those livers that were allocated based on the intestine match run.
6. Intestine Issues Working Group. During the April 2010 meeting, the Committee approved a proposal for public comment that would provide for broader sharing for liver-intestinal candidates, as these candidates have higher waiting list mortality than liver-alone candidates. However, during a call held in July 2010, several newly-appointed members had questions and concerns about the proposal and supporting data. The Committee received a summary of the prior data and analyses during the October meeting. An updated analysis confirmed that the death rates in adult candidates awaiting a liver-intestine are three-fold higher for those needing only a liver. The mortality rates remain higher even after a 10% increase in the MELD/PELD score was provided to these candidates. In contrast, it was reported that the national share for pediatric donors (age 0-11), implemented in 2007, has reduced the mortality for pediatric liver-intestine candidates such that it is comparable to liver-alone candidates. This is a small group of patients that have a very high death rate. The proposed national share would distribute the impact among most of the regions, such that regions with large intestine programs would not bear the full impact. The working group will continue to develop a proposal for public comment.
7. Joint Pediatric-Liver Subcommittee Split Liver Proposal. The Committee reviewed the proposal for split liver allocation developed by the Pediatric-Liver Subcommittee. Under the proposed algorithm, livers from donors under age 35 would be offered preferentially to very young pediatric candidates, for whom they would likely be split. During the April meeting, the following concerns were expressed:
  - Children already have good access to livers;
  - Split livers have worse outcomes in adults;
  - This will result in many reduced grafts;
  - Unlikely that children requiring Segment 2,3 grafts would use donors 18-21;

- This would disadvantage small women; and
- This would not increase number of split livers.

The Committee reviewed data intended to address these concerns, which showed that: waiting list mortality is highest for young children; graft and patient survival for splits versus whole are equivalent; and that very few splittable livers have led to reduced graft transplants. The majority of liver registrants indicate that they are willing to accept a segmental liver. However, split liver transplants represents only about 1.4% of all liver transplants. Nearly half of these transplants were performed in pediatric recipients, and most with MELD/PELD scores between 15 and 28. In 90% of split liver transplants, the pediatric candidate drives allocation. Policy currently provided guidance regarding which livers are to be considered suitable for splitting. However, there were more split liver transplants resulting from donors who did not meet the splittable criteria, suggesting that the criteria are not adequate. The proposed policy is estimated to result in as many as 88 more transplants for pediatric patients per year, which would be a 16.7% increase on pediatric transplants resulting from using 1.5% more donors for splitting.

Members expressed concerns about how the vessels are distributed when a liver is split for a pediatric patient. The policy current states that “The center getting the primary whole graft organ offer will determine the method of splitting and use of the vessels.” Any proposal for public comment would have to more clearly specify how the vessels would be distributed. Committee members also suggested that the proposal should require that the split occur at the donor hospital rather than at the pediatric center, where it then has to be shipped to the recipient center. Members noted that a proposal for broader sharing for donors aged 0-11 was approved in 2008 but has not been implemented yet, and suggested that the Committee should evaluate the impact of that policy change prior to making more changes.

8. MELD Enhancements Subcommittee. This Subcommittee was created after the April 2010 Forum and was charged to: evaluate potential incremental changes to the MELD score that will optimize the ranking of liver candidates by their medical urgency. The Subcommittee has met once, and requested a re-analysis of MELD-Na and the MELD refit of the upper and lower limits of the existing parameters.
9. Region 8 AAS (“Share 29”). The Region 8 “Share 29” AAS was implemented in May 2007, and the initial application specified an ending date of May 9, 2009 (two years). The Region later voted to extend this to November 8, 2009, to allow further analysis. Since the AAS has expired, and the OPTN Final Rule specifies that variances must be time-limited, the Committee should make a recommendation to the Board regarding its continuance. Data from the AAS has been reviewed during several committee meetings, during the Forum in April 2010, and at the American Transplant Congress in June 2010. The Committee has been considering the Region 8 AAS as a potential model for tiered-sharing that could be proposed for consideration as a national policy.

During the May 2010 Region 8 meeting, participants voted to dissolve the AAS. An official ballot was distributed, and 11 of the 16 participants favored dissolving the AAS, with 4 opposed and 1

abstention. Many of the comments from those wishing to dissolve the AAS indicated that the AAS did not provide any benefit to patients, while increasing costs to centers. Committee members questioned whether the limited impact of the AAS was related to the small number of patients and transplants involved. Other members noted that patients waiting for a combined liver-kidney transplant are not eligible for a kidney offer under the AAS, but were included in the analyses. The Committee asked for the analysis to be updated to exclude the liver-kidney candidates. The Committee also asked for the number of times a liver was offered to a candidate with a MELD/PELD score of 29 or higher as a result of the AAS, but was turned down by that candidate and transplanted into a candidate with a lower MELD/PELD score. The Committee agreed to review these data during the October 2010 meeting.

During the October 20, 2010, meeting, the Committee reviewed Policy 3.4.8.1, which provides the three options available to the Committee now that the AAS has expired:

“Initial approval by the Board of Directors of any AAD System shall be on a provisional basis for a period of 3 years. By the end of this period, the applicable Members must have demonstrated through objective criteria that the purpose for which the system was approved has been achieved or at least that progress considered adequate and demonstrated to the satisfaction of the reviewing committee(s)/Board to this end has been accomplished. At the end of the provisional approval period, the appropriate reviewing committees will recommend to the Board of Directors that the AAD System be: (a) finally approved, (b) approved on a continued provisional basis for a specific period of time, or (c) terminated.”

The Committee reviewed the three-year data for the AAS. All candidates ever listed on the liver waiting list in Region 8 between May 2004 and May 2010 were included in the analyses, which was stratified into the pre-AAS era (May, 9, 2004 – May 8, 2007) and the AAS-era (May 9, 2007 – May 8, 2010). This is the first time the Committee reviewed the three-year data. In summary, in the AAS era:

- There was a slight increase in number of livers transplanted;
- There was a 17% increase in the number of registrations ever having a MELD/PELD score of 29 or higher (those that met the criteria for regional sharing); Overall registrations increased 11%;
- There was more regional sharing of livers for candidates with MELD/PELD scores of 29 or higher;
- The overall pre-transplant death rate was unchanged despite increase in demand;
- The median MELD/PELD at transplant increased;
- The one-year graft and patient survival was unchanged;
- The median distance organ traveled increased 50 miles;
- Cold ischemia time was unchanged; and
- The length of stay increased by 1 day.

However, while not statistically significant, the data showed that the overall reduction in the risk of pre-transplant mortality was 10 percent (six percent when exceptions were included). This reduction, in light of the increased demand (defined by the number of registrations) of 11 percent, with an increase in supply (as defined by the number of deceased donors available for transplant) of less than five percent, showed a trend towards reduced mortality. The lack of statistical significance may be due to the small number of patients involved. The three-year analyses are the first that demonstrate a reduction in mortality, despite the increase in demand over the time period. The Committee asked that these analyses be revised with risk-adjustment.

The Committee has been considering tiered sharing, such as the Region 8 AAS, as a possible model for a national proposal. The U.S. House of Representatives' conference report that accompanied the 2010 Appropriations Bill states that, "Further, the conferees direct that any policy change on broader allocation of livers be tested first in demonstrations, similar to the demonstration recently conducted in Iowa and North and South Dakota, before nationwide implementation, and be made in an incremental manner, reflecting the accumulation and analysis of data on the impact of policy changes." Committee members felt that it is important to fully understand the potential impacts of such a system while there is a regional demonstration project currently in place. Additional data could include a power analysis, the share type (local, regional) and OPO type (single versus multiple center) for those recipients who received transplants with MELD/PELD scores less than 29. Committee members felt that extending the AAS for some specific period of time that would allow these additional analyses to be reviewed was important. Members also recognized that 69% of participants voted to discontinue the AAS, and expressed caution about enforcing an AAS on a region that has voted to discontinue it. Dissolution of the AAS will require programming in UNet<sup>SM</sup>, and there is no timeline currently available for when that programming would fall in the schedule of work. A motion to table a vote on the AAS was made, seconded, but then withdrawn. In light of the options provided in Policy 3.4.8.1, the Committee submits the following resolution for consideration by the Board of Directors:

**\*\* RESOLVED, that the Region 8 "Share 29" AAS shall be continued until June 30, 2011, pending further risk-adjusted analyses of the impact of the AAS.**

Committee Vote: 15 in favor, 1 opposed, 3 abstentions.

10. Status 1 Review Subcommittee. The Committee discussed the process for review of Status 1A/B cases not meeting criteria (NMC). Since 2005, all such cases have been reviewed by a subcommittee on a quarterly basis. The Subcommittee determined whether the cases were appropriate, inappropriate, or required further information. If a center had more than one inappropriate case for the same type of infraction, the cases were forwarded to the MPSC. In 2009, the Committee asked the Subcommittee to develop more specific criteria for review and referral. At that time the Subcommittee recommended that centers with more than one inappropriate Status 1 listing within the current year and two prior years should be referred to the MPSC. In April 2010, the Committee

asked the Board to reverse previously-approved policy language that would require review of these cases by the RRBs, as the Committee felt the subcommittee review process was working well. In August 2010, the Subcommittee began to review cases as they are listed, rather than on a quarterly basis. The cases are decided by a majority vote of the subcommittee. If case is determined to be inappropriate, the center is notified and provided with the following options:

- The center may voluntarily downgrade the patient to an appropriate status/score (only an option if candidate has not been transplanted). No further action will be required.
- The center may appeal the decision by submitting additional clinical information that supports listing at Status 1A/1B, and respond to comments of the reviewers. The subcommittee will re-review and vote again.
- The center may opt to maintain the 1A/1B Status, with the understanding that cases not resolved will be forwarded to full Liver Committee for further consideration. The Liver Committee may refer the case to the MPSC for additional review and consideration of disciplinary action.

The Subcommittee proposed that all centers with a single Status 1 case NMC should receive letters of education and warning, and include a description of the potential disciplinary action if an inappropriate listing occurs again. Centers with more than one inappropriate listing over a rolling 2 year period will be referred to full Committee and to MPSC if Committee agrees. The Committee asked that the new process be communicated to all centers, with clear guidelines and description of possible disciplinary action. The Committee will review this process in one year.

Several centers had more than one inappropriate case that was transplanted over the last year. The Subcommittee was concerned about referring cases to the MPSC if the center did not receive letters of warning. However, centers have been warned about listing patients with hepatic artery thrombosis (HAT) as Status 1A rather than a MELD of 40, per policy, including a letter to all the programs. Several of the cases involved HAT that should have been listed as MELD 40. Further, centers receive a warning whenever they list a patient as NMC that the listing could lead to referral to the Liver Committee and MPSC. A motion was made to send all these cases to the MPSC. This does not mean that the MPSC will take disciplinary action or imply any recommended consequence. Center behavior is likely to change upon referral to the MPSC. Another option would be to send all of them a letter citing the cases and patterns of behavior, and warning them that any future case would result in referral to the MPSC. The Committee approved the motion to refer all of these cases to the MPSC by a vote of 16 in favor, 0 opposed, and 0 abstentions.

The Committee also reviewed a summary of the review activity since August 2010. This includes one case listed prospectively that was determined to be inappropriate, and the patient was never listed as 1A/B. A letter will be sent all centers with a patient whose listing was deemed to be inappropriate, providing them details of the committee's comments and rationale. Cases where a patient is transplanted while in Status 1A/B and deemed to be inappropriate will be reviewed again by the subcommittee and committee.

11. MELD/PELD Exceptions Cases Not Approved in 21 days. The Committee reviewed three cases where a MELD/PELD exception application was not approved within the 21-day time frame set forth in the policy, the center decided to maintain the higher exception score, and the patient was transplanted. These are summarized as follows:

**WL\_ID #25732** – In this case, one RRB member did not vote even though the member was reminded several times. This caused the case to go beyond 21 days with no majority vote. The Committee voted to take no action by a vote of 15 in favor, 0 opposed, and 0 abstentions.

**WL\_ID #23723** – This case was from the same region and time frame as the prior case, with one member not voting. The Committee voted to take no action by a vote of 15 in favor, 0 opposed, and 0 abstentions.

**WL\_ID #27693** – In this case, the center appealed a denied initial submission on day 20. The Committee asked that the center to explain the circumstances of the case and the delay in their appeal, by a vote of 15 in favor, 0 opposed, and 0 abstentions.

12. New Business. The Committee approved a motion that UNOS allow centers to electronically transfer MELD/PELD data directly into UNet<sup>SM</sup> by a vote of 15 in favor, 0 opposed, and 0 abstentions. This would help eliminate human errors in data entry.

W. Kenneth Washburn, MD  
Committee Chair

Ann M Harper  
Policy Analyst