

**OPTN/UNOS Liver and Intestinal Organ Transplantation Committee**  
**Report to the Board of Directors**  
**November 16-17, 2009**  
**Orlando, Florida**

**Summary**

**I. Action Items for Board Consideration**

- The Board is asked to approve modifications to Policies 3.6.4.5 (Liver Candidates with Exceptional Cases), 3.6.4.5.1 (Liver Candidates with Hepatopulmonary Syndrome (HPS)), 3.6.4.5.2 (Liver Candidates with Cholangiocarcinoma), 3.6.4.5.3 (Liver Candidates with Cystic Fibrosis), 3.6.4.5.4 (Liver Candidates with Familial Amyloid Polyneuropathy (FAP)), 3.6.4.5.5 (Liver Candidates with Primary Hyperoxaluria) and 3.6.4.5.6 (Liver Candidates with Portopulmonary Syndrome). These modifications are intended to (a) clarify revisions made to the policy during the June 2009 Board meeting (b) correct several typographical errors and (c) clarify potentially confusing language (Item 2, pages 3-7).
- The Board is asked to approve modifications to the Regional Review Board Operational Guidelines that are necessary to implement Policies 3.6.4.5.1-3.6.4.5.6 without programming in UNet<sup>SM</sup> (Item 2, Pages 3-7).
- The Board is asked to reconsider the Committee's request to program Policies 3.6.4.5.1-3.6.4.5.6 in UNet<sup>SM</sup> (Item 2, Pages 3-7).

**II. Other Significant Items**

- The Committee is in the early stages of planning a public forum on liver distribution in the spring of 2010, as approved by the Board in June 2009. The Committee continues to examine transplant benefit and has begun examining alternative distribution concepts (Item 3, Page 7).
- The Committee discussed six proposals that had been circulated for public comment. (Item 4, Page 9).

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**W. Kenneth Washburn, MD, Chair**  
**Kim M. Olthoff, MD, Vice Chair**

*This report presents the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee's (Liver Committee) deliberations during its July 15, 2009 meeting, and October 6, 2009, conference call.*

1. Orientation and Committee Goals. The Committee received several brief orientations to OPTN/UNOS policy-making, UNOS research support, and support provided by the Scientific Registry of Transplant Recipients (SRTR) contractor. The Committee was reminded of its charge, as well as the annual goals set for 2009-2010:

- Continue to study and address geographic/regional variation and disparities in access to liver transplantation. Identify areas that can be addressed by the OPTN, and recommend appropriate approaches to addressing them;
- Update the HCC exception criteria based on recommendations from the consensus conference held in November 2008;
- Conduct evidence-based policy development for liver allocation to determine whether incorporating net benefit into liver allocation policy, at some point in the future, would further the OPTN long-range strategic goals and priorities; and
- Re-examine the feasibility of a national review board for MELD/PELD exceptions.

2. MELD/PELD Exceptions. In June 2009, the Board approved the Committee's proposal for standardized MELD/PELD exception criteria for six diagnoses, but the proposal was modified at the Board meeting. Several Board members expressed concerns about the requirement for uniform MELD/PELD score assignments across all regions, as candidates in some regions may need higher scores in order to receive an offer. The policy approved by the Board included new language stating that:

“Candidates meeting the criteria listed in 3.6.4.5.1 – 3.6.4.5.6 are eligible for additional MELD/PELD exception points, provided that the criteria are included in the clinical narrative. Unless the applicable RRB has a pre-existing agreement regarding point assignment for these diagnoses, an initial MELD score of 22/PELD score of 28 shall be assigned. For candidates with Primary Hyperoxaluria meeting the criteria in 3.6.4.5.5, an initial MELD score of 28/PELD score of 41 shall be assigned.”

Board members also expressed concern over the projected costs of programming the policy to support these ‘automatic’ exceptions. As proposed, diagnoses meeting the criteria would not require Regional Review Board (RRB) approval, but eligibility would be determined in UNet<sup>SM</sup>, similar to the programming for candidates with hepatocellular carcinoma (HCC)). The Board supported the standardized criteria and point assignments but did not support funding the programming.

During the July 2009 meeting, the Committee reviewed a list of questions related to policy implementation:

- How to reconcile the words “eligible” versus “shall” in the approved language?
- What if a Region has additional criteria?
- What if the RRB doesn't follow policy? Can this be enforced?
- What if an RRB wants a new agreement or wants to change their existing agreement?

- When should protocols for cholangiocarcinoma (CCA) be submitted and when will they be reviewed?
- How will the data for CCA be collected?

The MELD/PELD Exceptions Subcommittee was asked to address these questions and provide guidance to the transplant programs and RRB members. The Subcommittee was also asked to discuss alternate methods to collect data for candidates with these diagnoses, which was one of the goals of the proposal. The Subcommittee recommended the following changes/clarifications to the policy language:

- Modify the policy to state that only those agreements that assign higher MELD scores would be accepted;
- Require that Regional agreements must be renewed each year;
- Clarify that extensions receive a 10% mortality increase every 3 months;
- Modify Table 4 (criteria for cholangiocarcinoma (CCA)) to state that the “mass must be 3 cm or less; and
- Modify the diagnostic criteria in Table 4 for clarity.

The Subcommittee proposed a method for implementing this policy without programming. To facilitate uniform review of the applications, a template or checklist will be created for each diagnosis that would include all of the information required in the policy. The information could then be “pasted” into the narrative portion of the application. These templates will be distributed to all liver programs. The Subcommittee discussed whether the full RRB or only the RRB chair should review each application. One potential problem with a non-programming implementation of the policy is that an RRB could disapprove a case even if it meets the criteria, or approve a case that does not meet criteria. The most equitable process would be for the policy to be programmed. The Subcommittee recommended that, if it cannot be programmed, the RRB chair should review and approve those cases clearly meeting criteria. The RRB would review cases that the chair feels do not meet the criteria. If a case not is approved, and the center believes that the case meets the criteria, the center can appeal to the Committee. The Committee agreed with this recommendation.

The Subcommittee reviewed the existing agreements for Regions 3, 4, 7, 9 and 11. Some of the agreements suggested lower scores for one of the approved diagnoses (e.g., for oxaluria in Regions 3 and 4). These agreements would have to be rescinded if the Board approves the recommendation that only higher scores should be accepted. Otherwise, the Subcommittee felt that these should be extended for another year. One Committee member felt that the RRB should review each case, as there is benefit to having the members see the cases that are submitted, and the Regions should be able to set the scores. However, the policy as approved calls for consistent scores and criteria nationally. The Committee will study the impact of the policy change on candidates within each of the Regions following implementation. The briefing paper for these proposed changes is (**Exhibit A**).

The Committee submits the following for consideration by the Board of Directors:

- \*\* **RESOLVED, that Policies 3.6.4.5 (Liver Candidates with Exceptional Cases), 3.6.4.5.1 (Liver Candidates with Hepatopulmonary Syndrome (HPS)), 3.6.4.5.2 (Liver Candidates with Cholangiocarcinoma), 3.6.4.5.3 (Liver Candidates with Cystic Fibrosis), 3.6.4.5.4 (Liver Candidates with Familial Amyloid Polyneuropathy (FAP)), 3.6.4.5.5 (Liver Candidates with Primary Hyperoxaluria) and 3.6.4.5.6 (Liver Candidates with Portopulmonary Syndrome) shall be amended as set forth below, effective pending notice to the membership.**
- \*\* **FURTHER RESOLVED, that the RRB Operational Guidelines shall be amended as shown in (Exhibit B), effective pending notice to the membership.**

3.6.4.5 Liver Candidates with Exceptional Cases. Special cases require prospective review by the Regional Review Board. The center will request a specific MELD/PELD score and shall submit

a supporting narrative. The Regional Review Board will accept or reject the center's requested MELD/PELD score based on guidelines developed by each RRB. Each RRB must set an acceptable time for Reviews to be completed, within twenty-one days after application; 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; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws. Exceptions to the MELD/PELD score must be reapplied every three months; otherwise the candidate's score will revert back to the candidate's current calculated MELD/PELD score. If the RRB does not recertify the MELD/PELD score exception, then the candidate will be assigned a MELD/PELD score based on current laboratory values. Centers may apply for a MELD/PELD score equivalent to a 10% increase in candidate mortality every 3 months as long as the candidate meets the original criteria. Extensions shall undergo prospective review by the RRB. A candidate's approved score will be maintained if the center enters the extension application more than 3 days prior to the due date and the RRB does not act prior to that date (i.e., the candidate will not be downgraded if the RRB does not act in a timely manner). If the extension application is subsequently denied then the candidate will be assigned the laboratory MELD score. Candidates meeting the criteria listed in 3.6.4.5.1 – 3.6.4.5.6 are eligible for additional MELD/PELD exception points, provided that the criteria are included in the clinical narrative. Unless the applicable RRB has a pre-existing agreement regarding for a higher point assignment for these diagnoses, an initial MELD score of 22/ PELD score of 28 shall be assigned. For candidates with Primary Hyperoxaluria meeting the criteria in 3.6.4.5.5, an initial MELD score of 28/ PELD score of 41 shall be assigned. These pre-existing agreements must be renewed on an annual basis.

- 3.6.4.5.1 Liver Candidates with Hepatopulmonary Syndrome (HPS). Candidates with a clinical evidence of portal hypertension, evidence of a shunt, and a PaO<sub>2</sub> < 60 mmHg on room air will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase in points every three months if the candidate's PaO<sub>2</sub> stays below 60 mmHg. Candidates should have no significant clinical evidence of underlying primary pulmonary disease.
- 3.6.4.5.2 Liver Candidates with Cholangiocarcinoma. Candidates meeting the criteria listed in Table 4 will be will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months.
- 3.6.4.5.3 Liver Candidates with Cystic Fibrosis. Liver candidates with signs of reduced pulmonary function, defined as having an FEV<sub>1</sub> that falls below 40%, will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months.
- 3.6.4.5.4 Liver Candidates with Familial Amyloid Polyneuropathy (FAP). Candidates with a clear diagnosis, to include an echocardiogram showing the candidate has an ejection fraction > 40%, ambulatory status, and identification of TTR gene mutation (Val30Met vs. non-Val30Met) and a biopsy proven amyloid in the involved organ, will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months.
- 3.6.4.5.5 Liver Candidates with Primary Hyperoxaluria. Candidates with AGT deficiency proven by liver biopsy (sample analysis and/or genetic analysis), and listed for a combined liver-kidney transplant will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months. Candidates must have a

GFR ≤ 25 ml/min for 6 weeks or more by MDRD6 or direct measurement (Iothalamate or iohexol).

3.6.4.5.6 Liver Candidates with Portopulmonary Syndrome. Candidates that meet the following criteria will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months if the mean pulmonary arterial pressure (MPAP) stays below 35 mmHg (confirmed by repeat heart catheterization).

- Diagnosis should include initial MPAP and pulmonary vascular resistance (PVR) levels, documentation of treatment, and post-treatment MPAP < 35 mmHg and PVR < 400 dynes/sec/cm<sup>5</sup>.
- Transpulmonary gradient should be required for initial diagnosis to correct for volume overload.

**TABLE 4. Criteria for MELD Exception for Liver Transplant Candidates With Cholangiocarcinoma (CCA)**

- Centers must submit a written protocol for patient care to the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee before requesting a MELD score exception for a candidate with CCA. This protocol should include selection criteria, administration of neoadjuvant therapy before transplantation, and operative staging to exclude patients with regional hepatic lymph node metastases, intrahepatic metastases, and/or extrahepatic disease. The protocol should include data collection as deemed necessary by the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee.
- Candidates must satisfy diagnostic criteria for hilar CCA: malignant-appearing stricture on cholangiography and one of the following: carbohydrate antigen 19-9 100 U/mL, or biopsy or cytology results demonstrating malignancy, carbohydrate antigen 19-9 100 U/mL, or aneuploidy. The tumor should be considered unresectable on the basis of technical considerations or underlying liver disease (e.g., primary sclerosing cholangitis).
- If cross-sectional imaging studies (CT scan, ultrasound, MRI) demonstrate a mass, the mass should be 3 cm or less.
- Intra- and extrahepatic metastases should be excluded by cross-sectional imaging studies of the chest and abdomen at the time of initial exception and every 3 months before score increases.
- Regional hepatic lymph node involvement and peritoneal metastases should be assessed by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neoadjuvant therapy is initiated.
- Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative, or percutaneous approaches) should be avoided because of the high risk of tumor seeding associated with these procedures.

Committee Vote: 18 in Favor, 1 opposed, 0 Abstentions.

The Committee also submits the following for consideration by the Board of Directors:

**\*\* RESOLVED, that Policies 3.6.4.5 (Liver Candidates with Exceptional Cases), 3.6.4.5.1 (Liver Candidates with Hepatopulmonary Syndrome (HPS)), 3.6.4.5.2 (Liver Candidates with Cholangiocarcinoma), 3.6.4.5.3 (Liver Candidates with Cystic Fibrosis), 3.6.4.5.4 (Liver Candidates with Familial Amyloid Polyneuropathy (FAP)), 3.6.4.5.5 (Liver Candidates with Primary Hyperoxaluria) and 3.6.4.5.6 (Liver Candidates with Portopulmonary Syndrome) shall be programmed in UNet<sup>SM</sup>.**

Committee vote: 19 in favor, 0 opposed, 0 abstentions.

The Resource and Impact Statement for the interim ‘non-programming’ proposal is attached as **(Exhibit C)**. The Resource and Impact Statement for the original proposal, as submitted to the Board in June 2009, is attached as **(Exhibit D)**. The minutes of the Subcommittee’s call is attached as **(Exhibit E)**.

The Committee discussed the requirement for centers to submit a protocol in order for candidates with CCA to be approved with an exception. The Committee will develop a checklist to evaluate those protocols. The Subcommittee also recommended that staging and explant pathology should be made available (i.e., for audits) for all CCA cases with an exception.

#### *Transfer of Standardized MELD/PELD Exception Scores*

During the July meeting, the Committee discussed whether an approved MELD/PELD exception for a standardized diagnosis should transfer if a candidate moves to another Region (i.e., should the candidate’s approved score be maintained?). This question had been referred to the Committee after a candidate with an approved HCC exception moved to another Region, and his physician had petitioned the new RRB for a score equivalent to the score he had in his former region. Committee members felt that these scores should transfer. Candidates may have no control over where they are transferred due to their insurance coverage. The Committee felt that this should only apply to diagnoses with standardized criteria, such as HCC (meeting criteria) and the six newly-approved diagnoses. The Subcommittee will develop guidance for the review boards. The Committee approved the following:

*Motion: When a candidate receives a MELD/PELD exception for a standardized diagnosis, the score should transfer if the candidate transfers to another center. Committee vote: 19 in favor, 0 opposed, 0 abstentions.*

These cases could be managed in a similar fashion to the waiting time reinstatement process used for kidney candidates who transfer to another center. This will require a policy change that will follow the usual policy development process.

3. Initiatives Related to Broader Distribution / Improving Liver Allocation. In June 2009, the Board approved a resolution calling for a public forum on liver distribution to be held on the spring of 2010. Two subcommittees have been created to direct this work: a Public Forum Subcommittee and a Broader Distribution Subcommittee. The Committee will likely issue a Request for Information (RFI) in last 2009, which will help frame the questions and concepts that will be considered at the forum. Public comments received from the MELD/PELD regional distribution proposal will be reviewed for ideas that should be included. In addition to potential changes to the current local-regional-national distribution system, the forum may also include the concept of net benefit. The Committee considered a question as to whether the forum should be restricted to liver distribution only, or whether it should be broadened to include other organ types as well, perhaps with emphasis on liver. Committee members felt that broadening the scope of the forum would make the discussion too diffuse, and that it would make it difficult to come to any conclusions. However, this forum could be used as a springboard for other discussions.

#### *Public Forum Planning Subcommittee*

This Subcommittee met twice prior to the October 6, 2009 Committee conference call **(Exhibit F)** and **(Exhibit G)**. The Subcommittee discussed the structure of the forum, which would likely be a cross between the HCC Consensus Conference and the Kidney Allocation Forum. The intent of the forum would be to address a variety of ideas and concepts, rather than specific proposals, and to solicit input from a broad range of people/groups. This will require substantial preparation, much of which will be done by the Broader Distribution Subcommittee. Comments received on the RFI will feed into the forum content. The Committee discussed whether to conduct a brief survey of the membership about broad concepts related to organ distribution. The feedback from this could help to frame the RFI. Several Committee members offered to develop a brief poll that can be discussed at the November meeting.

### *Broader Distribution Subcommittee*

The Subcommittee has been discussing what is “feasible” for geographic sharing in terms of distance, ischemic time, driving versus flying, where increased distance leads to longer lengths of stay (LOS) and therefore poorer outcomes, etc (**Exhibit H**). The Subcommittee has requested a multivariable analysis of factors affecting LOS. The SRTR will also provide additional LSAM runs examining the impact of sharing at a benefit score of zero (similar to sharing at MELD 15). The Committee may consider different allocation systems (e.g. net benefit), as well as alternative distribution systems, such as using wider geographic areas. The Committee may explore each concept separately (i.e., allocation vs. distribution), and afterwards decide whether one or both will be discussed at the forum.

### *Review of Net Benefit Analyses*

In July 2009, the Committee received an overview of net benefit modeling and a summary of the SRTR’s work on the use of net benefit for liver allocation (**Exhibit I**). Transplant benefit is currently being used for lung allocation, and is also being considered for heart and kidney allocation. The Committee is looking at net benefit as one possible way to improve liver allocation. Transplant benefit combines the concepts of future wait-list lifetime with post-transplant lifetime, and reflects the number of life years gained through liver transplantation. The post-transplant model includes both recipient and donor factors. A “benefit score” is calculated for each MELD score. This benefit score increases as MELD increases, and is positive above a MELD score of 9. It was noted that two patients with equal MELD scores could have different benefit scores because MELD is not the only factor that predicts waiting list and post transplant mortality. There is also overlap in benefit between ranges of MELD scores. The index of concordance (IOC), which conveys the predictive ability of a model, is 0.75 for the waiting list model and 0.65 for the post-transplant model. In comparison, the MELD score has an IOC of 0.64.

Some Committee members felt that this concept will be difficult for patients to understand. Other comments and questions included:

- Should there be delisting criteria for those who are too sick?
- What is the impact on older candidates?
- These models do not account for long-term survival; and
- The model does not include cold ischemia time (CIT).

It was noted that ischemia time is not known until time of transplant, so it would be difficult to include in the score; further, ischemia time does not add much to the model when adjusted for other factors. Age plays a much less significant role for liver transplant survival than it does for kidney transplants.

The impact of transplant benefit was modeled using the LSAM simulation model and compared to the current liver allocation algorithm and to regional sharing for all candidates using MELD/PELD. Transplant benefit was projected to reduce total deaths by 102 and increase life-years saved over 5 years by 2,223 when compared to the current system. Transplant benefit did not appear to negatively impact any group of patients. In general, pediatric candidates have lower benefit scores, but due to age and size-matching for donors and the preference given to pediatric candidates for pediatric donors, these candidates do not appear to be disadvantaged by a net benefit system. As a next step, the concept will be applied to the allocation system in a similar fashion to “Share 15,” with some threshold of benefit score used for broader distribution of livers.

### *SRTR LSAM Modeling Results for Multiple Distribution Algorithms*

During a conference call in May 2009, the SRTR was asked to model several liver allocation algorithms using MELD/PELD threshold values of 22, 25, 29 and 35, for local followed by regional distribution (similar to “Share 15” but with different MELD/PELD thresholds). Several scenarios included full regional distribution

for the highest scores, while others incorporated 500-mile concentric circles as distribution units. The SRTR provided the number of projected pre- and post-transplant and total deaths and changes in distance travelled for each scenario (**Exhibit J**). Committee members expressed the following concerns:

- An area of 500 nautical miles is too large for the “local” unit;
- Distance could be based on driving versus flying as a logical cut-point;
- The models do not include effect of increased CIT on morbidity and survival;
- The Committee will need to assess costs as increased distance leads to increased travel time/costs, and ischemia time; and
- Will such a system lead to higher quality donors leaving the local area DSA and poorer donors staying?

While these are valid concerns, it was noted that these models are a starting point for discussion, and such concerns will be considered as the Committee looks at alternatives. Each option considered by the Committee will have consequences and trade-offs. The Committee must first frame the question: is the goal to minimize waiting list deaths? How will this impact post-transplant outcomes/survival benefit? One Committee member proposed that the goal is to minimize waiting list mortality without a significant increase in costs/distance and outcomes.

4. Proposals Circulated for Public Comment. The Committee discussed six proposals that had been circulated for public comment in June 2009.
  - Proposal to Improve the ABO Verification Process for Living Donors. This proposal brings the policy for double ABO verification of living donors in line with the policy for deceased donors. The Committee was unanimously in support of this proposal.
  - Proposed Guidance for the Medical Evaluation of Living Liver Donors. These guidelines were modeled after the Living Kidney Donor Guidelines that have been approved by the Board. Some Committee members expressed concerns that these types of guidelines should be developed by the professional societies. Other Committee members requested more time to review the document, and voted to defer comments until it has time for more review and discussion. Committee vote to defer comment: 15 in favor, 3 opposed, and 0 abstentions.
  - Committee members forwarded comments via e-mail, including specific changes to the document in “track changes,” which were provided to the Living Donor Committee. Other comments included:
    - The lengthy list of specific tests for donors is not appropriate; the medical professional societies should develop medical recommendations.
    - Regardless of the statement that “This resource is not a policy or bylaw. The OPTN contractor will not monitor adherence to these guidelines,” some regulatory agency will view them as such.
    - HCV should be tested in all donors (also reiterating that the list of tests should not be included).
    - The risks need to be put into context by comparing risks that are the same for non-donors. There should also be comparison to some standard risk scale (such as riding a certain number of miles by car or by motorcycle). Statements such as “Donors have reported chronic problems including bile strictures, re- operations, and chronic pain” are not particularly helpful.
  - Proposal to Add Language to the Bylaws Requiring Transplant Center and OPO Members to Follow State Law Regarding Anatomical Gifts. The Committee was in support of this proposal that requires centers to follow their own state laws regarding end of life care and organ recovery. A reference showing where the state laws can be found would be helpful. Committee vote: 18 in favor, 0 opposed, and 0 abstentions.
  - Proposal to Change the Bylaws to Reconcile Discrepancies in Patient Volume Requirements for Full and Conditional Program Approval When Qualifying Kidney, Liver and Pancreas Primary

Transplant Physicians. This proposal would make the bylaws regarding patient volume requirements internally consistent. The Committee was in support by a vote of 18 in favor, 0 opposed, and 0 abstentions.

- Notification Requirements for OPOs, Transplant Hospitals, and Histocompatibility Labs When Faced with an Adverse Action Taken by Regulatory Agencies. The MPSC is proposing a change in the number of days by which a member must notify the MPSC when faced with an adverse action by a regulatory agency. One Committee member asked whether the proposed change would diminish the performance-monitoring function of the MPSC. One approach would be to separate the notification from the submission of required materials. No vote was taken as the proposal does not specifically apply to liver/intestine transplantation.
- Proposal to Change Requirements for Labeling and Packaging Organs Procured by Visiting Transplant Center Teams and for OPO Labeling of Tissue Typing Materials. This proposal would transfer the responsibility of packaging and labeling of organs from the OPO to the transplant center when its recovery team elects to recover an organ and transport it directly to their transplant center for transplant. Sometimes the recovery teams opt to forgo the required labeling procedure, which leaves the OPO out of compliance with policy. Committee members felt that the labeling requirements should be enforced, and that OPOs should be required to report these centers to the MPSC, rather than simply transfer the responsibility to the center. The Committee did not support this proposal by a vote of 1 in favor, 18 opposed, and 1 abstention.

5. Intestine Issues Working Group. This working group is charged with responding to requests by the Committee or subcommittees related to intestine transplantation issues. The working group includes several individuals who are not on the Committee who have substantial experience with intestine transplantation. A summary of the group's August 20, 2009 conference call is attached as **(Exhibit K)**.

#### *Criteria for Intestinal Transplant Surgeons and Physicians*

Several years ago, the Committee developed criteria for intestine transplant surgeons and physicians that were circulated for public comment. The proposal was criticized by many as being "too restrictive," and some felt it would impair development of intestinal transplant programs and the field of intestine transplantation in general. The proposal was not forwarded to the Board. Subsequently, the ASTS developed criteria for intestinal transplant fellowship training programs for surgeons. The ASTS requires that a surgeon perform 10 transplants and 5 procurements, either through volume during the fellowship or through experience over 2-5 years. A subcommittee was formed to review these criteria for possible inclusion in the Bylaws.

The Subcommittee chair reviewed the current requirements for other organs to determine whether the intestine criteria seemed reasonable, based on the number of transplants performed annually in the US. Currently, six intestine transplant programs would meet the ASTS requirements for a fellowship training program based on their transplant volume, but none is listed on the ASTS website as being approved. The Subcommittee felt that 10 transplants and 5 procurements would be an appropriate number to set for the surgical director of an intestine transplant program. As there is currently no equivalent of a hepatology fellowship, the Subcommittee recommended that the requirements for intestine physicians would be obtained via the experience pathway. For the physician, the Subcommittee proposed a requirement of 10 patients followed for 3 months post-transplant, either during a hepatology or GI fellowship or as an attending physician on a transplant service, with some combination of isolated intestine and combined liver-intestine transplant recipients. The individual would also be required to view at least one isolated and one combined liver-intestine transplant and to be involved in the evaluation of one multi-organ donor. Some Committee members felt that limiting the surgeon experience pathway to 10 per year may be too few, while others felt it may be difficult to obtain that volume.

During the October conference call, the Subcommittee reported that one member had been tasked with proposing an alternative pathway for intestine programs that may have a long history of intestine transplantation but do not currently meet the proposed volume requirements.

### *Request to Change the Liver-Intestine Allocation Policy*

The Committee received a letter from a Member asking for a change to the adult intestine allocation system in a similar fashion to the pediatric intestine allocation system, to reduce the adult mortality rate for these candidates (**Exhibit L**). The Intestine Subcommittee was asked to review this request and make a recommendation to the full Committee.

The Subcommittee requested an update of the SRTR's analysis in 2005 that led to the proposal for increased priority for liver-intestine candidates. They also requested an analysis of how often the liver-intestine is placed from the intestine waiting list versus the liver waiting list, and how often the liver is included in the offer to the intestine waiting list. The Subcommittee will reconvene when these data are available.

6. Joint Liver-Pediatric Subcommittee. A joint Subcommittee of the Liver/Intestinal and Pediatric Transplantation Committees was asked to review several policies related to pediatric candidates and make evidence-based recommendations to the Liver and Pediatric Committees. These include:
  - Criteria for Status 1A/1B;
  - Allocation to candidates with incompatible blood type;
  - Requirements candidates with hepatoblastomas; and
  - Allocation of split livers.

### *Status 1A/1B Criteria*

Policy 3.6 states that a candidate must be located in an Intensive Care Unit (ICU) to meet Status 1A/1B criteria. The Committee reviewed a memorandum from the MPSC stating that some liver transplant programs list candidates as Status 1A or 1B while they are admitted to telemetry or step down units (**Exhibit M**). The MPSC expressed concern that location is being used as a surrogate for severity of illness, and “may encourage costly and inefficient behavior patterns by some transplant centers that admit candidates to an ICU exclusively to achieve adult 1A (i) and pediatric 1A or 1B status on the Waitlist.” The MPSC requested that the Pediatric Transplantation and Liver and Intestinal Organ Transplantation Committees “reevaluate the current listing criteria that require candidates to be admitted to the ICU to achieve status 1A/1B and determine whether the use of candidate location (ICU) as a surrogate for severity of illness remains appropriate and advisable.” Committee members discussed the valid reasons why a critically ill patient may not be admitted to the ICU (e.g., no ICU beds, patient not intubated or on vasopressors). Step-down and telemetry units were not felt to be equivalent to an ICU. The Committee felt that there is currently a mechanism for a center to justify why a candidate was not in the ICU via the narrative, and that the policy should not be changed.

The Pediatric Transplantation Committee reviewed this memorandum, and felt that the ICU requirement could perhaps be removed for pediatric candidates. The Committee requested data to determine how often a candidate does not meet Status 1A/B criteria solely because the candidate was not in the ICU. The joint Subcommittee reiterated this request. The Subcommittee will also review the differences between the adult and pediatric criteria for hepatic artery thrombosis (HAT) for Status 1A to determine if they should be made consistent.

### *Analysis of ABO-incompatible Liver Transplants.*

Policy 3.6.2.2 (Liver Allocation to Candidates Willing to Accept an Incompatible Blood Type) states that “For Status 1A or 1B candidates or candidates with a match MELD or PELD score of 30 and greater, centers may specify on the Waiting List those candidates who will accept a liver from a donor of any blood type.” During the November 2008 meeting, the Committee reviewed a request to revise the existing liver allocation policy requirements regarding incompatible ABO transplants to be similar to that used in thoracic organ allocation. The thoracic organ allocation policy states that “Following allocation for all born transplant candidates who have blood types that are compatible with donors, hearts will be allocated locally first and

then within zones in the sequence described in 3.7.10, by heart status category to born Status 1A or 1B pediatric heart candidates who are eligible to receive a heart from any blood type donor.” The policy also lists specific criteria regarding which candidates are eligible to accept a heart from any blood type donor.

The Committee asked for current data about ABO incompatible liver transplants in order to evaluate this request. OPTN/UNOS data for deceased donor liver transplants between January 1, 2003 and October 31, 2008 were included in the analysis (**Exhibit N**). Graft and patient outcomes were computed using standard Kaplan-Meier survival rates for deceased donor liver transplants between March 1, 2003 and December 31, 2006. Cases where blood type A<sub>2</sub> donors were transplanted into O recipients were considered compatible and excluded from the analyses. There were 118 transplants with incompatible blood type matches, or 0.3% of the transplant cohort. Approximately 50% of cases were adults, and 80% were listed in Status 1/1A/1B at the time of transplant. The age distribution was normal in adults, but in pediatrics was concentrated in the youngest age groups. ABO incompatible transplants had the lowest graft/patient survival, although these were also the sickest candidates. The lowest graft survival for ABO incompatible transplants was for those with a calculated MELD/PELD score of 30 or higher, while patient survival was similar for MELD/PELD scores less than 30 as compared to 30 or higher. The survival rates were better for pediatric patients than for adults. The Committee asked that the Joint Liver-Pediatric Subcommittee review the data and the policy and make a recommendation to the Committee.

#### *Split Liver Allocation Policy*

The Subcommittee was asked to revisit the policy for allocation of split livers, which was put into place several years ago. The intent of the policy was to incentivize splitting, but it does not seem to be having that effect. During the Subcommittee call, members discussed ways to increase the use of split livers, including:

- Increase the age cut-off for pediatric preference similar to the kidney allocation algorithm, which would direct more young and “splittable” livers to smaller candidates; the right lobe could be allocated to an adult.
- Incentivize splitting by allowing the center that accepts a split liver to use both segments in their own patients.

A Committee member also suggested that candidates who are willing to accept a segment could be given additional MELD/PELD points.

#### *Candidates with Hepatoblastoma*

Policy 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma) states that candidates with non-metastatic hepatoblastoma can be listed at a MELD/PELD score of 30 for 30 days, after which the candidate may be listed as a Status 1B. Recent studies indicate that patients with limited metastatic disease who are resected have good outcomes. Often the resection surgery is delayed until several rounds of chemotherapy have been given, which delays the candidate’s listing and the ability to be listed as a Status 1B. One option is to eliminate the 30-day waiting time at MELD/PELD 30. Another option is to allow candidates with metastatic disease be included in the policy. The Subcommittee will continue to explore these options and will report to the full Committees.

7. Status 1A/1B Review Subcommittee. All Status 1A/1B cases that do not meet the criteria in outlined in policies 3.6.4.1 (Adult Candidate Status) or 3.6.4.2 (Pediatric Candidate Status) are reviewed by a subcommittee. Each case is reviewed by three subcommittee members, and reviewers do not review cases from their own Region. If all three reviewers are in agreement that a case is appropriate, then no further review occurs. Otherwise, the Subcommittee reviews the details of case, and a recommendation is made to the full Committee. If a center is referred for the first time, typically the Committee will send a letter of education or warning, while repeat offenders are referred to the Membership and Professional Studies Committee (MPSC). In the past, the Subcommittee considered repeat violations as only those violations of

the same criteria (e.g., PNF outside the time limit in policy), but did not consider infractions for different criteria as repeat offenses. The Subcommittee will now review a center's history of cases as a whole. The Subcommittee was asked to develop more specific criteria for how cases are reviewed and referred to MPSC (i.e., how many infractions within some period of time). Now that regional distribution for Status 1 candidates has been approved by the Board, it is especially important for the Committee to provide close oversight of these listings.

During the October call, the Subcommittee reported that it had reviewed the Status 1A/1B listings for 26 candidates that did not meet the criteria in policy (**Exhibit O**). Several centers will likely be referred to the MPSC. A member suggested that cases referred to the MPSC should be accompanied with the details of the case being referred, as well as the prior cases that did not meet criteria from that center. The Subcommittee felt that many of the cases warranted letters of education. In several instances, the Subcommittee asked for more information prior to making their recommendation. In response to the Committee's request, 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. The full Committee will review the cases and recommendations during the November 2009 meeting.

8. HCC Consensus Conference. The meeting report from the conference held on November 2009 was submitted for publication in early July. Some of the recommendations may be incorporated into the liver allocation policy. The HCC policy also needs to be updated and revised/reorganized. A subcommittee was formed to review the conference recommendations and the current policy. Several members of the imaging working group have received funding from the American College of Radiology Imaging Network (ACRIN), which is part of the National Cancer Institute (NCI), for a multi-center trial that will compare pre-transplant imaging studies with post-transplant pathology. The Board voted to endorse the ACRIN project in June 2009. The Subcommittee will be asked to assist with developing the RFI for this trial.
9. Bylaws Pertaining to Liver Transplant Physicians. The MPSC asked that the Committee provide input regarding the bylaws pertaining to liver transplant physicians (**Exhibit P**). The current bylaw is problematic because there are individuals who may be well-trained but do not meet the specifics of the bylaws. Centers who are recruiting a primary liver transplant physician may not know whether a candidate will be approved by the MPSC prior to hiring, and the MPSC does not have the ability to grant waivers for individuals who may have experience but lack the appropriate boards. Further, it is hard to document "foreign equivalent" training. The MPSC asked for feedback on the following:
  - Should the bylaws be expanded to include a pathway for individuals who have completed a transplant hepatology fellowship but did not complete a GI fellowship?
  - Should the board certification requirements be amended to allow Transplant Hepatology as an alternative to Gastroenterology Boards?

A subcommittee has begun to review these issues, which are complicated because several related factors are still in flux: the certificate of added qualification (CAQ) in transplant hepatology that was approved in 2008, as well as the movement for a separate board in transplant hepatology to obtain subspecialty training during a gastroenterology fellowship, which may be 5-7 years away. Committee members recommended that feedback should be obtained from the American Association for the Study of Liver Disease (AASLD), American Society for Transplantation (AST), American Gastroenterology Association (AGA), and American College of Gastroenterology (ACG). This may also be a topic for the program directors meeting at Digestive Disease Week (DDW) this year.

10. Proposed Listing Requirements for Simultaneous Liver-kidney (SLK) Transplant Candidates. A proposal for listing requirements for candidates awaiting an SLK transplant was circulated for public comment in February 2009, but was not forwarded to the Board due to questions about implementation. The proposal included specific criteria for those candidates needing an SLK, plus a "safety net" for those not meeting the criteria who subsequently need a kidney transplant following a liver-alone transplant. These two aspects of the policy

would have to be programmed at the same time. However, the number of kidney alternative allocation systems (AASs) makes changes to the kidney algorithm very complicated. Further, it is likely that this may not be programmed until the new kidney allocation system (KAS) is implemented. If the policy were to be put forward without the safety net, it would require another round of public comment. A joint subcommittee of the Liver and Kidney Committees will address these issues.

11. 2009 Fall Regional Meetings. The Regional Representatives were reminded of their responsibility to present the Committee's ongoing activities at the fall meetings. The Committee reviewed the standard slide set that will be presented and suggested modifications (**Exhibit Q**).

**Committee Attendance at the  
July 15, 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.	X
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.	by telephone
Maureen Burke-Davis, RN, NP-C, CCTC	At Large	by telephone
Patricia Carroll PA-C, CPTC	At Large	X
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	
Elizabeth Pomfret, M.D., Ph.D.	Ex Officio	X
Bernard Kozlovsky, M.D., MS	Ex Officio, HRSA	X
Monica Lin, Ph.D.	Ex Officio, HRSA	X
Mary Guidinger, MS	Arbor Research	X
Robert Merion, M.D.	Arbor Research	X
Douglas Schaubel, Ph.D.	Arbor Research	X
Ann Harper	Committee Liaison	X
Erick Edwards, Ph.D.	UNOS Research Support Staff	X

**Committee Attendance at the  
October 6, 2009 Committee Meeting  
Conference Call**

NAME	COMMITTEE POSITION	In Attendance
W. Kenneth Washburn, M.D.	Chair	X
Kim Olthoff, M.D.	Vice Chair	X
Michael Curry, M.D.	Regional Rep.	X
Stephen Dunn, M.D.	Regional Rep.	
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.	X
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	X
Julie Heimbach, M.D.	At Large	X
Heung Bae Kim, M.D.	At Large	X
Timothy McCashland, M.D.	At Large	
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	
Bernard Kozlovsky, M.D., MS	Ex Officio, HRSA	X
Monica Lin, Ph.D.	Ex Officio, HRSA	X
James Bowman, MD	Ex Officio, HRSA	X
Mary Guidinger, MS	Arbor Research	X
Robert Merion, M.D.	Arbor Research	X
Douglas Schaubel, Ph.D.	Arbor Research	X
Emily Messersmith	Arbor Research	X
Ann Harper	Committee Liaison	X
Erick Edwards, Ph.D.	UNOS Research Support Staff	X
Jory Parker	UNOS Business Analyst	X