

**OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Report to the Board of Directors**

**June 22-23, 2009
Richmond, Virginia**

Summary

I. Action Items for Board Consideration

- The Board is asked to grant final approval to modifications to Policy 3.6 (Allocation of Livers), which will create regional distribution of livers for Status 1A and 1B candidates. This proposal was circulated for public comment, reviewed and recommended by the Policy Oversight Committee (POC) for Board consideration. (Item 1, page 5)
- The Board is asked to approve a public forum on liver distribution, to be held in the Spring of 2010. (Item 1, page 7)
- The Board is asked to grant final approval to modifications to 3.6.4.5 (Liver Candidates with Exceptional Cases). This will provide standardized criteria and MELD/PELD scores for six diagnoses. This proposal was circulated for public comment, reviewed and recommended by the POC for Board consideration. (Item 2, page 9)
- The Board is asked to grant a continuation of the Ohio Statewide liver alternative allocation system (AAS) for up to three years. The AAS will be re-evaluated on an annual basis and may be dissolved by the Board prior to the end of the three year period. (Item 3, Page 13)
- The Board modifications to Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) to clarify that the largest dimension must be reported for each tumor entered into the HCC exception application. These proposed changes were not circulated for public comment as they are clarifications of existing policy. (Item 4, Page 13)
- The Board is asked to approve a modification to the HCC exception application in UNetSM that would reinstate the “No appeal/No withdraw” (“override”) button for denied exceptional case applications. The Board is also asked to approve modifications to Policies 3.6.4.3 (Pediatric Liver Transplant Candidates with Metabolic Diseases), 3.6.4.4. (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC) and 3.6.4.5 (Liver Candidates with Exceptional Cases), to reflect the requirement that a conference call must be held prior to this option being utilized. These proposed modifications were not circulated for public comment as they are not substantive changes to the policy. (Item 5, Page 14)

II. Other Significant Items

- The Committee discussed the HCC Consensus Conference that was held in November 2008. (Item 6, Page 16)

- The Committee received an update on the Region 8 Alternative Allocation System (AAS). (Item 7, Page 16)
- The Committee received an update on the potential use of net benefit for liver allocation. (Item 8, Page 17)
- The Committee received an update on the covariates used in the Program Specific Report (PSR). (Item 9, Page 17)

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Elizabeth A. Pomfret, MD, PhD, Chair
W. Kenneth Washburn, MD, Vice Chair

This report presents the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee's (Liver Committee) deliberations during its November 19, 2008, and March 31, 2009, meetings and May 14, 2009, conference call.

Review of Committee-sponsored Public Comment Item, February 2009

1. Proposals to Create Regional Distribution of Livers. The Committee submitted two proposals for public comment in February 2009 that would eliminate "local" from the liver distribution algorithm. The two proposals, one for Status 1A/1B candidates and the other for candidates listed with a MELD/PELD score, were submitted separately.

Regional Distribution for Status 1A/1B Liver Candidates.

A detailed description of this proposal is provided in **Exhibit A**. As of the March 31, 2009, Committee meeting, 49 comments had been submitted, with 74% of those comments having an opinion in support of the proposal. Some comments in opposition were actually in reference to the proposal for regional distribution for MELD/PELD candidates. Of the regions that had met, Regions 1, 6, and 10 were in support and Region 2 opposed. In Region 2, there were concerns about one DSA that reportedly has higher rates of listing Status 1 candidates than other DSAs in the Region, with many being for primary non-function (PNF) or hepatic artery thrombosis (HAT). There were also concerns that there could be two Status 1 candidates in a region with similar waiting time (e.g., listed one day apart), resulting in organs "crisscrossing" in the air, leading to unnecessary shipment of livers.

During the May 14, 2009, conference call, the Committee reviewed the public, committee, and Regional comments that had been received on this proposal (**Exhibit A**). Eight committees were in favor (Ad Hoc International Relations, Organ Availability, OPO, Patient Affairs, Pediatric Organ Transplantation, Policy Oversight, and Transplant Coordinators) and two were opposed (Operations and Transplant Administrators). Nine Regions were in support and two opposed (Regions 2 and 3). The American Society of Transplant Surgeons (ASTS) and American Society of Transplantation (AST) were in support of the proposal.

As of the public comment deadline on April 24, 2009, UNOS had received 337 individual responses, with 88 (26.1%) in support of the proposal, 238 (70.6%) opposed, and 11 (3.3%) with no opinion. Of the 326 who responded with an opinion, 88 (27.0%) were in favor and 238 (73.0%) opposed. There were several complicating factors with the responses received; specifically, that 46% of responses (65% of those opposed) were from individuals from one state, and 24% of negative responses actually appeared to relate to MELD/PELD proposal and not the Status 1 proposal. To further confuse the tallies, many letters did not specify which of the distribution proposals that the commenter was commenting upon. There were 363 comments mailed or e-mailed to UNOS that appear to be opposed to both proposals; these had not been entered into the system or the response tally. Finally, there

were duplicate responses (website, e-mail, and paper copy), many of them form letters, and many received past the public comment deadline.

The Committee discussed the primary objections to the proposal, which can be summarized as follows:

- Will hurt local donation / Local organs should stay local;
- Issues with use of waiting time as tie-breaker;
- Increased costs and air travel;
- Will hurt small programs/ limit access;
- Will result in poor outcomes;
- Should consider for fulminant hepatic failure (FHF);
- The change would have a limited impact;
- Issues with the policy development process/timeline;
- Need more data; and
- The Regions are arbitrary.

The Committee noted that the vast majority of the Regions and committees, plus the ASTS and AST were in support of this proposal. The Committee discussed suggestions that the proposal should apply to candidates with FHF only. When the proposal was initially discussed by the Committee, the SRTR provided modeling results showing the impact of national sharing for fulminant cases only. The results suggested that Status 1 candidates may get transplanted “too quickly” with national sharing (i.e., sometimes it takes a day or two to find out if the patient will recover from the liver injury without a transplant). Further, the number of candidates is very small. The Committee felt it made sense to restrict the proposal to Regional distribution, but not to candidates with FHF only. Committee members suggested that it is important for the transplant community to understand that these concepts had been discussed by the Committee. Committee members felt that many of the other comments were not based on any data or evidence.

Responses to these comments can be found in the proposal briefing paper (**Exhibit A**). Per UNOS Bylaws, Appendix C, 1.03C, “Public comments received by the close of the public comment period shall be reviewed and responded to by the reviewing Committee(s). Comments received after the response deadline may be reviewed and responded to at the discretion of the Chair(s) of the reviewing Committee(s). Following consideration of the comments and any additional information requested by the Committee(s), the Committee(s) shall make any modifications to the proposal deemed appropriate, including dismissal of the proposal for further consideration. The policy briefing paper shall be updated to include responses to the public comments and the final proposal.” For the convenience of the reader the responses are provided as follows. Due to the large number of comments received, often with the same verbiage, responses have been provided for each of the ten major recurrent themes that appear throughout the comments. The Committee submits the following for consideration by the Board of Directors:

**** RESOLVED, that Policy 3.6 (Allocation of Livers) shall be amended as set forth below, effective pending programming in UNetSM and notice to the membership.**

3.6 ALLOCATION OF LIVERS.

<< No changes to introductory paragraph >>

At each level of distribution, adult livers (i.e., greater than or equal to 18 years old) will be allocated in the following sequence (adult donor liver allocation algorithm):

Adult Donor Liver Allocation Algorithm

Combined Local and Regional

1. Status 1A candidates in descending point order

Regional

~~2. Status 1A candidates in descending point~~

Combined Local and Regional

~~2.~~ 3. Status 1B candidates in descending order.

Regional

~~4. Status 1B candidates in descending point order~~

<< No further changes to Policy 3.6 >>

Committee Vote: 9 in favor, 2, opposed, 1 abstention

The Resource and Impact Statement for this proposal can be found in **Exhibit B**.

Regional Distribution of Livers for MELD/PELD Candidates.

As of the March 31, 2009, Committee meeting, 142 individual responses had been submitted, and 71% of the comments submitted with an opinion were in support of the proposal. Regions 2, 6, and 10 were opposed to the proposal, and Region 1 was in support. Comments made during the regional meetings and by the public include:

- Costs to transplant centers had not been assessed;
- DSA sizes and recovery practices vary widely across the country;
- Could lead to increases in ischemia and travel time, especially with extended criteria donors (ECD);
- Potential for increased turn-downs and discards;
- Concerns about impact on small- and medium-sized programs and access to transplant;
- Organs leaving the local area may decrease support for local organ donation;

- Could create operational issues with candidates having multiple simultaneous offers;
- May create staffing problems for small centers wanting to send their surgeons for procurements; and
- The predicted increase in distance could lead to more air travel.

There was discussion at the Region 2 meeting about other ways to broaden distribution, perhaps using a threshold of 29 or 30, or using distance from the donor rather than the current geographic boundaries. Members in Region 10 felt that this proposal was not suited for their region due to the potential for increased distances traveled, more air travel, and increased costs to centers with little predicted benefit. Several regions and commenters indicated that broadened distribution at some level would be a good idea, whether it would be above a specific MELD/PELD score, or whether distance from the donor hospital might be considered, as both DSA and Regional designations are arbitrary.

The Committee agreed that some form of tiered approach, as suggested by several regions and the ASTS, could be modeled by the SRTR using LSAM. One member suggested that the MELD/PELD threshold could be different for each region, based on the mean MELD at transplant, as some regions have higher average MELD scores at transplant. However, much of the reported “MELD creep” is likely caused by scores assigned to exceptions granted in some regions. Further, this type of threshold is not related to the candidates’ risk of death on the waiting list. The complexity of the programming would also be prohibitive.

Elizabeth Pomfret, MD, Committee Chair, reminded the Committee that not every proposal that is circulated for public comment is submitted to the Board, and that sometimes proposals require further development and public input. Since there was no compelling evidence to select a specific threshold, such as 29, the proposal included distribution for all MELD/PELD scores. This has been misunderstood by some in the transplant community. The regional representatives were asked to explain the policy development process during their presentations at their regional meetings, and to elicit constructive comments. The Committee supported the concept of having a public forum to discuss the issue of allocation/distribution (16 in favor, 3 opposed, 1 abstention).

During the May 14, 2009, conference call, the Committee reviewed the public, Committee, and Regional comments that had been received on this proposal. Dr. Pomfret noted this was a highly controversial proposal, and informed the Committee that she and others from UNOS met in Washington, DC with staff members from a congressional Committee (Health, Education, Labor and Pensions (HELP)) to discuss the Regional sharing proposal in April.

Four Committees were in support of the proposal (Ad Hoc International Relations, Patient Affairs, Policy Oversight, and Thoracic) and five opposed (Operations, OPO, Organ Availability, Transplant Administrators, Transplant Coordinators). Two Regions were in support (1 and 9) and the remaining nine were opposed. As of April 24, 2009, 1866 individual responses had been submitted. Of the 1,856 who responded with an opinion, 158 (8.5%) were in support and 1698 (91.5%) were opposed. Letters of opposition were received from members of Congress from Wisconsin, South Carolina, Indiana, Oklahoma, Utah, and Kentucky. The ASTS opposed the proposal while the AST was in favor of it. There were several issues that made the public comment difficult to interpret:

- 64% of the negative responses were from one state;

- Many did not cite which proposal(s) (Status 1 or MELD/PELD or both);
- Duplicate responses submitted (via website, e-mail, and paper copy);
- There were many form letters; and
- Many letters were submitted after the deadline.

The Committee received constructive comments, many of which had been discussed during the March meeting. For example, while the costs of the proposal have not been assessed, there may be data available from the Region 8 AAS. The logistical difficulties posed by multiple offers coming in through DonorNet[®] should also be evaluated. There were many suggestions to use a MELD/PELD threshold or tiered approach, distance from the donor rather than the DSA or Region, and/or incorporating net benefit. Many of the criticisms were similar to those submitted for the Status 1 proposal (and may in fact have been meant for the Regional distribution proposal). Many comments were critical of the policy development process. Some stated that the proposal was distributed without any “warning” and that the proposal was on a fast-track to the Board. Dr. Pomfret noted that, during the meeting in Washington, representatives from transplant programs in attendance stressed these issues. In one case, the Regional Representative from the Liver Committee did not attend the fall 2008 Regional meeting, and therefore the proposal was not presented. This caused members in that Region to be surprised by the proposal, even though the proposal had been in development for more than a year. Dr. Pomfret stressed the responsibility of Regional Representatives to attend both the Regional and Committee meetings. One suggested method to improve communication is for the Committee to send a newsletter to the liver transplant community prior to and following Committee meetings.

The Committee discussed the proposal for a holding a public forum on distribution, to be held in the Spring of 2010, to continue this dialog with the community and to identify ways to improve liver distribution. Members stressed the importance of engaging with the transplant societies, and advocacy and patient groups. In preparation for the July 15, 2009, meeting, the Committee asked that the SRTR model various scenarios using either different thresholds for regional sharing (MELD/PELD 22, 25, 29, 35) and/or a tiered approach. Members discussed replacing the DSA as the local unit with some other structure, such as distance or population density. Committee members discussed whether there are any data to support or disprove the idea that local allocation drives local donation efforts. The potential impact on costs would also be important to have available for the forum. The Committee submits the following recommendation to the Board of Directors for its consideration:

**** RESOLVED, that the Liver and Intestinal Organ Transplantation Committee will sponsor a public forum on liver distribution in the Spring of 2010.**

Committee Vote: 10 in favor, 1 opposed, 0 abstentions.

If approved, a subcommittee will be formed in July to start planning the forum. The Committee did not vote to forward the proposal for regional distribution for MELD/PELD candidates to the Board, in effect tabling the proposal until after the forum.

2. Proposal for Standardized MELD/PELD Exception Criteria and Scores. A detailed description of this proposal is provided in **Exhibit C**. During the May 14, 2009, conference call, the Committee reviewed the public, committee, and Regional comments that had been received on this proposal. Six

Committees were in support of the proposal (Ad Hoc International Relations, Patient Affairs, Pediatric Organ Transplantation, Policy Oversight, Transplant Administrators, Transplant Coordinators) and one opposed (Operations). Nine regions were in support, with Regions 7 and 9 opposed to at least one of the diagnoses. There were 95 individual responses submitted. Of the 85 who responded with an opinion, 69 (81.2%) were in favor and 16 (18.8%) were opposed. The ASTS was in support of the proposal, but felt that the point allocations were arbitrary. Comments in opposition could be summarized as:

- Issues with proposed scores or criteria for individual diagnoses;
- The scores should be set by each Region
- MELD Score of 22 not based in evidence

Hepatopulmonary Syndrome (HPS). Much of the opposition to the proposal appeared to be with the choice of MELD 22 as a starting point. In Regions 7 and 5, there was some concern that the recommendation is different from that of the published paper from the MELD Exceptions Study Group (MESSAGE) conference, which recommended a tiered score based upon the degree of hypoxemia. However if a candidate needs a higher score due to mortality risk then the center may petition the RRB. In Region 9, members felt that these cases should be decided by the RRB. Some Regions suggested that the scores should be set by each Region. This would likely require very complex programming, and having different scores in each region could be confusing. Further, having standardized, objective criteria and data collection will enable better assessment of these diagnoses in the future.

The Committee noted that the scores were ultimately set at 22 to be consistent with the HCC cases, which are the majority of the exceptions. This seemed a reasonable starting point. The mortality risk is difficult to estimate for some diagnoses due to small numbers. The Committee agreed that these scores should be updated if the MELD score assigned for HCC exceptions changes. The Committee has also made a commitment to review data related to these diagnoses after implementation. One commenter stated that it is difficult to show evidence of a shunt, however this requirement is in the policy currently, but was inadvertently marked as deleted in the public comment document. The sentence “Candidates should have no significant clinical evidence of underlying primary pulmonary disease” was also mistakenly deleted and has been reinstated in the final version of the policy. The Committee voted to forward this to the Board by a vote of 11 in favor, 0 opposed, and 0 abstentions.

Cholangiocarcinoma (CCA). There seemed to be a misunderstanding by some commenters that the policy would require centers to use the Mayo Clinic’s protocol, which is not the case. The proposed policy would require centers to submit a protocol, which must include neoadjuvant therapy, to the Liver Committee prior to requesting a MELD/PELD exception for candidates with CCA. Committee members felt that this should be a national policy rather than letting each region set their own standards. The data from the Mayo clinic have been published and committee members felt the evidence for these criteria is strong. The Committee voted to forward this to the Board by a vote of 11 in favor, 0 opposed, and 0 abstentions.

Cystic Fibrosis. Several comments noted that the criteria are too restrictive. However, the threshold for FEV₁ was established by the MESSAGE conference. If a center wants to request an exception for a candidate that does not meet the criteria or feels that a higher score is necessary, the center can always petition the RRB. The Committee voted to forward this to the Board by a vote of 11 in favor, 0 opposed, and 0 abstentions.

Familial Amyloid Polyneuropathy (FAP). One commenter noted that “this may lead to an increase in the number of hearts that are pulled from the local thoracic candidates since, depending on which lists the OPO allocates from first, this could lead to a multi-organ offer ahead of sicker thoracic patients.” A Committee member noted that this comment came from her OPO, and that the proposed policy actually assigns a lower score than is assigned in that Region now. The Committee agreed that the policy should require a biopsy, per the MESSAGE guidelines, so the phrase “and/or a biopsy” should be revised. The Committee voted to forward this to the Board by a vote of 11 in favor, 0 opposed, and 0 abstentions.

Primary Hyperoxaluria. Several comments were made regarding the cost and availability of genetic testing and the proposed MELD/PELD score assignment. The higher score for these cases was selected because the Committee felt that there is more urgency for candidates with this diagnosis, and the need for a combined liver-kidney transplant requires a higher score in many regions.

After discussion of the first five diagnoses, the Committee agreed that all six diagnoses should be included in the proposal. Responses to each comment can be found in **Exhibit C**. The Committee submits the following to the Board of Director for its consideration:

**** RESOLVED, that Policy 3.6.4.5 (Liver Candidates with Exceptional Cases) shall be amended as set forth below, effective pending programming in UNetSM and 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 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.

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 PaO₂ < 60 mmHg on room air will be listed at a MELD score of 22 without RRB review with a 10% increase in points every three months if the candidate’s PaO₂ stays below 60 mmHg. ~~referred to the RRB for consideration of a MELD score that would provide them a reasonable probability of being transplanted within 3~~

~~months. Candidates should have no significant clinical evidence of underlying primary pulmonary disease.~~

~~3.6.4.5.2 Liver Candidates with Familial Amyloidosis or Primary Oxaluria. Candidate with familial amyloidosis or primary oxaluria may be referred to the RRB for consideration of a MELD score that would allow them to be transplanted within 3 months.~~

3.6.4.5.2 Liver Candidates with Cholangiocarcinoma. Candidates meeting the criteria listed in Table 4 will be listed at a MELD score of 22 without RRB review with a 10% 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 FEV₁ that falls below 40%, will be listed at a MELD score of 22/PELD score of 32 without RRB review with a 10% 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/or a biopsy proven amyloid in the involved organ, will be listed at a MELD score of 22/PELD score of 32 without RRB review with a 10% 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 listed at a MELD score of 28/PELD score of 41 without RRB review with a 10% 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 listed at a MELD score of 22 points with a 10% 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⁻⁵.
- 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 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.
- 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: 11 in favor, 0 opposed, 0 abstentions

The Resource and Impact Statement for this proposal can be found in **Exhibit D**.

3. Further Review of the Ohio Statewide AAS. In the Fall of 2008, the Committee recommended to the Board that several AAS's should be dissolved based on its review of the applications and data provided during the AAS review project. In November 2008, representatives from the Ohio Solid Organ Transplant Consortium (OSOTC) presented additional information to the Executive Committee. The Executive Committee approved a resolution stating that "the recommendation to discontinue to the Ohio Statewide sharing agreement shall be referred to the Liver and Intestinal Organ Transplantation Committee for further deliberation based upon the additional information presented by the Ohio Solid Organ Transplantation Consortium." During the March 2009 meeting, Charles Miller, MD, from the Cleveland Clinic, presented the data and rationale for the Ohio Statewide AAS, and suggested that it might be applicable to a larger paradigm (**Exhibit E**). He noted that there special circumstances in Region 10 and Ohio:
 - Ohio has 4 OPOs while Michigan and Indiana have only one OPO each;
 - Policy 3.6 allows for "local" allocation before regional placement, but this presumes that local allocation within a region is equitable;
 - Without this agreement, areas of Ohio will be transplanting lower MELD patients while higher MELD patients would not receive an available organ;

- Application of a single rigid national allocation algorithm to variable definitions of local and regional can lead to inequitable allocation and distribution; and
- AAS's have been and remain the sole means to apply novel allocation algorithms to special geographic such as situations found in Region 10 that result in equitable allocation solutions.

Dr. Miller stated that the AAS has provided equitable allocation of deceased donor livers among all potential liver recipients in Ohio, while not adversely impacting the equitable allocation of organs in the remainder of Region 10. He suggested that the AAS achieves the primary goals of the Final Rule without discriminating against candidates on the basis of their place of residence or listing. He provided data showing the percentage of local and regional organ transplants, transplant rates, waiting times, and survival rates. Dr. Miller addressed statements made by the Liver and the Policy Oversight Committees that the AAS restricts sharing and has exceeded the duration of an ‘experiment,’” as it has been in place for 20 years. The current application has an experimental design and is time-limited to 3 years, during which time the OSOTC will utilize the SRTR’s LSAM model. The liver transplant programs from the other states in the Region had submitted letters of support for the AAS, which the Liver Committee had not seen previously. Dr. Miller noted that one OPO and its transplant center are opposed to the AAS, but that policy requires support from 75% of the parties, and the AAS currently has 80%. Additionally, the Ohio State Department of Health intends to mandate the AAS for liver transplant programs in Ohio. He noted that the relationship is currently reciprocal for all livers in Michigan and Indiana, and, without this reciprocity, the patients of Ohio would clearly be disadvantaged. In summary, Dr. Miller suggested that the “tiered approach” balances the conflicting principles of transplanting the sickest candidates first with promoting local organ procurement and cost reduction, and should be considered for national policy. One Committee member acknowledged that this system appears to “fix” the situation with the OPOs in Ohio so that Ohio is like Indiana and Michigan, but asked if full regional distribution for all MELD/PELD scores had been considered. Dr. Miller said that Ohio is open to any concepts of broader sharing; however, this AAS has been in place for 20 years and can provide important prospective information. At this point, the OSOTC representatives were asked to leave the room.

Committee members were unsure how the LSAM modeling would be utilized. The stated plan is to use the model to determine what the impact would have been if the AAS was not in place. However, this modeling could be done currently, without waiting for 3 years. One compelling argument of Dr. Miller’s presentation was that the DSAs are arbitrary, and that if their “local” area were all the DSAs in Ohio, it would meet the spirit of broader sharing, and might be a useful experiment. However, it was noted that “state” has not been recognized by policy as an allocation unit, and is also arbitrary. Perhaps one approach is to encourage DSAs that are close to one another to create a “local” unit, rather than use state as local. Committee members mentioned that the other two statewide sharing agreements (Florida and Tennessee) were dissolved by the Board, and approving this may call into question the decision made for the other two. Ultimately, the Committee felt that if this AAS is better for patients then it should continue, and the other states can resubmit their AASs for reconsideration. It was reported that the “de-programming” of the Florida and Tennessee AASs is underway and bundled with other programming projects, and the Board would have to rescind its vote in order for those AASs to continue. The Committee agreed to allow the AAS to continue in light of the new information and analysis plan, but asked the OSOTC to:

- Provide more detailed goals and objectives;

- Provide annual updates to the Liver Committee;
- Consider redefining “local” for their AAS as multiple DSAs or investigate new models, noting that, without a change, the LSAM “experiment” is not an experiment.

The Committee may rescind the agreement on an annual basis. The AAS would also be dissolved if a new national allocation policy is approved in the interim. The Committee submits the following resolution to the Board for its consideration:

**** RESOLVED, that Ohio Statewide liver alternative allocation (AAS) system shall be continued for up to three years. The AAS will be re-evaluated on an annual basis, and may be dissolved by the Board prior to the end of the three year period.**

Committee Vote: 11 in favor, 4 opposed, and 5 abstentions.

The Resource and Impact Statement for this proposal can be found in **Exhibit F**.

4. Memoranda from the UNOS Department of Evaluation and Quality (DEQ) regarding HCC Exceptions. The Committee discussed several questions from DEQ related to HCC exceptions (**Exhibit G**). First, the UNetSM application requests a one dimensional measurement for each tumor reported. However, policy does not specify that the largest diameter of a tumor be reported. Site auditors have noted cases where the largest tumor dimension was not reported, which, if reported, would have changed the outcome of the application approval. For example, if a tumor is 3.0cm by 5.2cm, and the center reports 3.0cm, then the application would be approved as a Stage T2, even though the tumor is larger than a Stage T2. To address this issue the Committee submits the following resolution to the Board for its consideration:

**** RESOLVED, that Policy 3.6.4.4 shall be amended as set forth below, effective pending programming in UNetSM and notice to the membership:**

3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC). Candidates with Stage II HCC in accordance with the modified Tumor-Node-Metastasis (TNM) Staging Classification set forth in Table 3 that meet all of the medical criteria specified in (i) and (ii) may receive extra priority on the Waiting List as specified below. A candidate with an HCC tumor that is greater than or equal to 2 cm and less than 5cm or no more than 3 lesions, the largest being less than 3 cm in size (Stage T2 tumors as described in Table 3) may be registered at a MELD/PELD score equivalent to a 15% probability of candidate death within 3 months. The largest dimension of each tumor must be reported (i.e., 3.2cm x 5.1cm must be reported as 5.1cm).

<< **No further changes to 3.6.4.4** >>

Committee Vote: 20 in favor, 0 opposed, 0 abstentions.

Per Bylaw Appendix C, Section 1.03C (Evaluation), this modification was understood as a means to “clarify or correct existing policy rather than substantively change policy” which does not require the policy change to be circulated for public comment (**Exhibit H**).

The Committee was also asked how centers should document treatment with TheraSphere[®] within the HCC exception application. This is a new treatment therapy that is not currently an option for members to select as a type of chemoembolization. The Committee felt that the HCC exception

application in UNetSM shall be amended to include “radiation microspheres” as an option for ablative therapy.

Current policy does not include a timeframe for submission of the explant pathology reports. The DEQ memorandum noted that there is a wide variation in the time frame that these reports are submitted to UNOS. The Committee agreed that the policy should include some timeframe consistent with other data release policies (20 in favor, 0 opposed, 0 abstentions). Currently, the Transplant Recipient Registration forms must be submitted within 60 days of the form generation date. This will be circulated for public comment.

5. Denied Exceptional Case Applications and the “21-Day Rule.” Policy 3.6.4.5 states that “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 patient’s transplant physician may list the patient at the higher MELD or PELD score, subject to automatic referral to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.” When this policy was approved in November 2001, the 21-day time frame was intended to provide adequate time for dialogue between the physician and the RRB, while allowing the treating physician to make the ultimate decision regarding the candidate’s listing, with the knowledge that the case would be referred to the Liver Committee and potentially the MPSC. When first implemented, the listing center could select the “no appeal/no withdraw” (“override”) button on the application after a denial by the RRB. If this button was selected, the candidate would be assigned the requested score, with a warning that the case would be referred to the Liver Committee and potentially the MPSC. The button was last utilized by a center in 2003, and was inadvertently removed when a modification to the policy was subsequently implemented. Listing physicians still have the option of last-minute appeal of denied cases, but the Committee did not feel that is an appropriate solution. The Committee recommended that the “no appeal/no withdraw” should button be reinstated. The Committee further recommended that it should only be used after an appeal to the RRB and a conference call. These cases would still result in automatic review to the Liver Committee. This will require programming, as well as changes to the policy in the three sections that address the “21-day” timeframe. Per Bylaw Appendix C, Section 1.03C (Evaluation), these modifications were understood as a means to “clarify or correct existing policy rather than substantively change policy,” which does not require the policy change to be circulated for public comment (**Exhibit I**).

The Committee submits the following to the Board of Directors for its consideration:

**** RESOLVED, that the “No appeal/No withdraw” button for denied exceptional case applications shall be reinstated, and that Policies 3.6.4.3 (Pediatric Liver Transplant Candidates with Metabolic Diseases) 3.6.4.4. (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC) and 3.6.4.5 (Liver Candidates with Exceptional Cases) shall be amended as set forth below, effective pending programming in UNetSM and notice to the membership:**

3.6.4.3 Pediatric Liver Transplant Candidates with Metabolic Diseases. A pediatric liver transplant candidate with a urea cycle disorder or organic acidemia shall be assigned a PELD (less than 12 years old) or MELD (12-17 years old) score of 30. If the candidate does not receive a transplant within 30 days of being listed with a MELD/PELD of 30, then the candidate may be listed as a Status 1B. Candidates meeting these criteria will be listed in as a MELD/PELD of 30 and subsequent Status 1B without RRB review. Hospitalization is not a requirement for listing in Status 1B for these candidates. Candidates with other metabolic diseases may apply to the Regional Review Board for an appropriate PELD (less than 12

years old) or MELD (12-17 years old) score. Decisions by the Regional Review Boards in these cases shall be guided by standards developed jointly by the Liver/Intestinal Organ Transplantation and Pediatric Transplantation Committees. In such cases the requested score must receive prospective approval by the applicable RRB within twenty-one days after application; if approval is not given and the physician wishes to pursue the listing, then the physician and the RRB must meet by conference to review the case; ~~if approval is not given~~ within twenty-one days, the candidate's transplant physician may list the candidate at the higher PELD or MELD 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.

<< No further changes to 3.6.4.3 >>

3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC).

<< No changes until the following text >>

If the initial request is denied by the RRB, the center may appeal via a conference call with the RRB but the candidate will not receive the additional MELD/PELD priority until the case is approved by the RRB. Cases where the appropriate RRB has found the listing center to be out of compliance with Policy 3.6.4.4 will be referred to the Liver and Intestinal Organ Transplantation Committee for review and possible action. Cases not resolved within 21 days will be referred 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.

<< No further changes to 3.6.4.4 >>

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 and the physician wishes to pursue the listing, then the physician and the RRB must meet by conference call to review the case; ~~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.

<< No further changes to 3.6.4.5 >>

Committee Vote: 16 in favor, 1 opposed, 1 abstention.

The Resource and Impact Statement for this proposal can be found in **Exhibit J**.

6. Report from the HCC Consensus Conference, November 2008. Dr Pomfret reported that the reports from the working groups have been combined into one document that is being edited. The pathology, imaging, and loco-regional ablation/down-staging reports may be submitted to journals as separate papers. The Committee reviewed the explant pathology reporting form proposed by the Pathology Work Group (**Exhibit K**). Current policy requires that a post-transplant pathology report must be submitted if a candidate is transplanted with an HCC exception. The new form will provide uniformity in reporting the post-transplant pathology results and would replace the current system of faxed forms. The OMB Forms Subcommittee had reviewed the form during a conference call, with minor suggestions. The Committee proposed to require the form for all candidates with HCC, regardless of whether the candidate had an HCC exception application. The question “Was evidence found of HCC in the explant” would be added to the Transplant Recipient Registration (TRR) form, and, the new form would be generated if this is checked ‘yes.’ One concern expressed was whether the transplant centers receive the pathology reports within the reporting timeframes for TRR forms. The Committee approved the form by a vote of 20 in favor, 0 opposed, 0 abstentions.

Dr. Pomfret discussed the Imaging Working Group’s proposed classification system for liver imaging. The Working Group developed minimal technical specifications for scanners (CT/MRI). Based on this, they developed a standardized reporting system for tumors, ranging from Class 0 (Incomplete or technically inadequate study) to Class 5 (meets radiologic criteria for HCC), as well as imaging criteria for Class 5 lesions. Finally, the Working Group created a reporting template for CT or MRI. Changes will be made to Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) to incorporate use of the classification system and the reporting template; this will be circulated for public comment in the spring of 2009. Members of the Working Group have also begun a multi-center study that would combine the imaging criteria with the pathology results.

7. Update on the Region 8 Alternative Allocation System (AAS). As part of the ongoing discussion about broader distribution, the Committee received an update on Region 8’s “Share 29” AAS (**Exhibit L**). The Committee reviewed data for one year prior and one year following the implementation of the AAS (May 9, 2007). The Committee had previously reviewed the 6-month data when it was formulating the Status 1 and MELD/PELD distribution proposals. These data had been presented at the Region 8 meeting in December 2008. In summary, the results show:

- No change in liver utilization;
- Modest (7%) increase in the number of MELD/PELD 29+ registrations;
- More regional sharing of livers for MELD/PELD 29 and higher;
- Overall pre-transplant death rate decreased, but was not statistically significant;
- MELD/PELD distribution at transplant relatively unchanged; and
- Based on first 6 months after implementation, graft survival unchanged.

Surendra Shenoy, MD, Region 8 Representative, was asked about the increased costs due to the AAS. He noted that the shift from local to regional was approximately 20% (30% to 50% Regional). Because of the AAS, centers can turn down offers for ECD donors for their higher MELD candidates as there is a higher likelihood of getting a better liver due to the AAS. Centers may also turn down offers from great distances because another, closer offer may come soon. These types of behavioral effects were seen after the implementation of “Share 15” policy. The members of Region 8 felt that

there was benefit to the Region, and voted to continue the AAS for another 2 years. They will continue to review the data every six months.

8. Update on Net Benefit Allocation System Modeling. During the November 2008 meeting, representatives from the SRTR provided an update on the modeling for net benefit liver allocation system (**Exhibit M**). The update included the impact on pediatric patients by modifying the benefit formula and the impact of a benefit-based allocation system on HCC patients. The results showed that although the average rank of pediatric cases would decrease under the new system, the number of pediatric transplants and deaths among pediatric patients would be unchanged. For those with HCC, the analysis showed that although the number of transplants would decrease, the number of deaths would decrease and a substantial number of life years would be saved. It was also noted that with a benefit-based system, different HCC patients would be transplanted than under the current system. The Committee and the SRTR will continue to evaluate the potential impact that a net-benefit allocation system might have on other candidate groups, including liver-intestine candidates. The Committee requested more information on the impact of HCC candidates and transplants.

In March 2009, the Committee received an update on the SRTR's benefit-based modeling (**Exhibit N**). Earlier LSAM simulations focused on the number of total and transplants and deaths, life-years gained from transplantation, the distribution of transplants by recipient age, and whether the recipient had HCC. The current simulations are focused on the distribution of age, race, gender, and diagnosis, as well as the specific characteristics of patients with HCC and those receiving a combined liver-intestine transplant. The Committee reviewed the results of two regional distribution proposals. Compared with distribution using MELD/PELD scores, benefit-based allocation resulted in slightly older patients being transplanted (but otherwise similar in race and gender) and with a very different distribution of MELD/PELD scores. The model predicted increases in transplants in the 15-19 MELD/PELD category and decreases in the 20-24 category. While LSAM predicted a slightly lower percentage of transplants for candidates with HCC, there were fewer deaths among these patients, because those with higher benefit would be transplanted. Transplanted HCC patients had similar tumor characteristics under both systems. Both models resulted in a similar percentage of liver-intestine transplants, and similar distribution of deaths (pre- and post-transplant) for those patients. The SRTR is considering several possible modifications to benefit score, to include:

- Post-transplant survival model: Allowing the model to have hazard ratios that vary over time and reevaluating previous time on list as predictor;
 - Wait list survival model: Including history of deactivation and simultaneous listing for intestine; and
 - Evaluating possibility of expanding time horizon beyond 5 years, which would possibly advantage younger candidates.
9. Program Specific Report (PSR) Subcommittee. The SRTR had updated eight of the PSR models (adult and pediatric deceased and living donor 1- and 3-year graft and patient survival), but were unable to produce the pediatric living donor 1- and 3-year patient and graft survival models due to the small number of events. The SRTR supplied a list of all the current covariates to each of the eight models (**Exhibit O**). The Committee asked that the Pediatric Committee review the pediatric PSRs, so that the Committee can vote on all the models once the feedback from the Pediatric Committee has been received. The Committee discussed the problem with missing data values, which may be advantageous for some centers as it makes their patient mix seem to be sicker than in actuality. The Subcommittee recommended that missing values should be assigned the lowest hazard value to deter use of missing data values.

10. Data Collection Forms Subcommittee. UNOS must resubmit the data collection forms to the federal Office of Management and Budget (OMB) every three years. The Committee reviewed the objectives of and timeline for the OMB submission process (**Exhibit P**). A proposal will be sent for public comment in August 2009. The final proposal will be submitted to the OMB in the summer of 2010 with an implementation date of November 2010. Any new data element collected must (1) meet one of the OPTN Principles of Data Collection; (2) be approved by the Policy Oversight Committee; and (3) be circulated for public comment. The Subcommittee reviewed the Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), and Transplant Recipient Follow-up (TRF) forms, as well as recommendations from other Committees and the SRTR. The Subcommittee recommended the following:

Revisions:

- Revised causes of graft failure (PNF, HAT, Recurrent disease, other vascular thrombosis (or complications), diffuse cholangiopathy, other) as reason for listing, to replace “primary graft failure”;
- Add definition of exhausted vascular access “as loss of 2 or more vascular access site” to intestine medical factors at listing;
- Current primary and secondary diagnosis codes for liver and intestine forms:
 - Replace AHN with acute liver disease;
 - Replace “Cirrhosis Type A” with “chronic liver disease/cirrhosis: viral hepatitis A” and similar changes to other ‘Cirrhosis’ diagnoses; and
 - Spell out “secondary biliary cirrhosis” and “metabolic disease”.

Additions:

- Graft failure and cause as reason for listing;
- Concurrent hepatic condition(s) as reason for listing;
- Has the candidate/recipient ever had a diagnosis of HCC at listing, transplant;
- Current malignancies at listing, between listing and transplant;
- Hepatoblastoma at listing, transplant;
- Cholangiocarcinoma (if yes, neoadjuvant therapy y/n);
- Add (total) bilirubin (listing, transplant, follow-up) to the intestine forms;
- Add GVHD and ischemia/NEC (necrotizing enterocolitis) like syndrome as an option to primary cause of graft failure;
- New intestine medical factors (at listing): variceal bleeding in the last 2 weeks, recurrent sepsis, fungal sepsis, unmanageable fluid-electrolyte losses, non-reconstructible GI tract;

and

- Explant pathology form.

Deletions

- Cause of graft failure: primary graft failure.

Did not recommend (provided by other Committees)

- Living donor graft weight (LDR);
- Cause of graft failure: donor related categories;
- More details if vascular thrombosis is listed as cause of graft loss;
- Arterial reperfusion date/time at transplant; and
- Biliary complications (at discharge and follow-up, up to 5 years) / If yes: Leak, stricture, anastomotic, non-anastomotic, diffuse cholangiopathy.

The Committee accepted the Subcommittee's recommendations, with minor revisions, by a vote of 17 in favor, 0 opposed, 0 abstentions.

Robert Merion, MD, presented a list of co-morbid conditions that are not currently collected but may affect waiting list- and post-transplant survival, and could be used in the PSRs as well. The SRTR also proposed that forms should be modified to allow the selection of multiple diagnoses, and, for all candidates with HCC, serial measurement of size and number of nodules and ablative therapy. Currently, there are little or no data for candidates who have HCC but do not have an exception. The Forms Subcommittee will review the list of co-morbidities and make a recommendation.

11. Review of Policies and Bylaws Issued for Public Comment on October 10, 2008 and February 5, 2009. During the November 2008 and March 2009 meetings, the Committee reviewed several proposals developed by other Committees that had been circulated for public comment.
 - a. Proposal to allow candidates who need a pancreas for technical reasons as part of a multiple organ transplant to be listed on the pancreas waiting list. (Combined Kidney-Pancreas Waiting List Criteria) (Pancreas Transplantation Committee). The Committee supported this proposal by a vote of 14 in favor, 0 opposed, 0 abstentions.
 - b. Proposal to increase the safety of allocations to candidates who do not appear on the match run (MPSC). The Committee supported this proposal by a vote of 14 in favor, 0 opposed, 0 abstentions.
 - c. Proposal to clarify, reorganize, and update OPO policies to align with current practices. (OPO Committee). The Committee supported this proposal by a vote of 11 in favor, 1 opposed, 0 abstentions.
 - d. Proposal to modify the high risk donor policy to protect the confidential health information of potential living donors (Living Donor Committee). One Committee

member asked what would happen if a donor had engaged in high-risk behavior and wanted to go ahead with the donation, and whether that would be reported to the potential recipient. The Committee had no other comments.

- e. **Proposed Listing Requirements for Simultaneous Liver-Kidney (SLK) Transplant Candidates.** This proposal is intended to establish minimum criteria for candidates listed for SLK transplantation in order to identify candidates who are unlikely to regain renal function following liver transplantation. The proposal also includes a “safety net” provision for candidates that do not meet the criteria for a SLK and do not regain their renal function post-transplant. As of March 31, 2009, 83% of the comments submitted were in support of the proposal. There was concern that the proposal does not make clear that candidates should have cirrhosis, and how this would be documented, as well as concerns about the cut-point for and estimation of GFR. One commenter questioned whether kidneys would be allocated to candidates awaiting a kidney-pancreas rather than to those in need of a kidney following a liver transplant. Committee members felt that the kidney-related questions should be referred to the Kidney Committee. Due to the complexity of issues related to implementation of this policy, the proposal will not be forwarded to the Board in June 2009.
12. **Guidelines for Liver Transplant Anesthesiologists.** The Committee has been collaborating with the American Society of Anesthesiologists (ASA) to develop criteria for liver transplant anesthesiologists. The ASA Transplant Committee, which is composed of anesthesiologists from across the nation with representation from all specialties of organ transplantation, has drafted guidelines that would define the expertise needed for a chief of anesthesia of a liver transplant program. During the November 2008 meeting, these guidelines were provided for the Committee’s review. This draft version had not been fully reviewed by the ASA Transplant Committee nor adopted by the ASA House of Delegates. A finalized proposal will be submitted to the ASA House of Delegates for its, and if the House of Delegates accepts the proposal into the ASA bylaws, they will take effect in October 2009. If criteria are established there would be a grace period after which all programs would have to comply with these criteria. There was some concern that the currency requirement (i.e., in terms of recent experience) has not yet been defined. Members noted that guidelines for pediatric transplantation will probably require a separate recommendation because the numbers are so small.

During the March 2009 meeting, Susan Mandell, MD, addressed the Committee regarding the status of these collaborative efforts (**Exhibit Q**). Dr. Mandell’s purpose was to ask the Committee to help create a “durable structure for anesthesiologists to develop policy, practices and integrative networks with other transplant subspecialties.” She presented data indicating that anesthesia care affects liver transplant patient outcome, and that outcomes are improved with sub-specialization (Hevesi Z, et al, 2009 Liver Transpl (in press)). This study revealed that the introduction of a specialized anesthesia transplant team led to decreased use of blood products and ICU resources. Dr. Mandell stressed that there is an unacceptably wide variation in anesthesia practices in the U.S. She described the work of the Liver Transplant Anesthesia Consortium (LTrAC), which collects and catalogues information on anesthesia practices. Three surveys have been conducted or are ongoing:

- LTrAC 101 - Determined how anesthesia departments organized LT services.
- LTrAC 201 - Measured the frequency and distribution of specific intraoperative practices
- LTrAC 301 (in progress) - Measures the frequency and distribution of specific perioperative practices

These surveys showed that (1) most liver transplant anesthesiologists are not part of an integrated transplant team, and (2) anesthesiologists recognize the importance of additional training. The proposed pathway is to integrate liver transplant anesthesiologists into transplant organizations at the national level (e.g., ASTS) to foster subspecialty development, assist with policy development, and assist with identifying best practices. Kerri Wahl, MD, anesthesiology representative, agreed that there is no consistency nationally regarding how anesthesia departments are organized in terms of generalists versus sub-specialties. For liver and lung transplantation, the importance of defining subspecialties for transplant anesthesia expertise has been recognized. Dr. Wahl summarized the draft guidelines, which recommend that:

1. All liver transplant programs designate a Director of Liver Transplant Anesthesiology;
2. The Director of Liver Transplant Anesthesiology shall be a Diplomat of the American Board of Anesthesiology or hold an equivalent certification from another country;
3. Within the last two years, the Director shall have had:
 - a. Fellowship training that includes the inter-operative care of at least 10 liver transplant recipients, or
 - b. Post-training experience in the inter-operative care of at least 20 liver transplant recipients;
4. Directors shall earn a minimum of 8 hours of CME credit in transplant related activities within the most recent 3 year period; and
5. Upon ASA approval these guidelines shall be forwarded to the UNOS Committee on Liver Transplantation for their consideration.

There may be additional guidelines for directors of pediatric liver transplant anesthesiology groups if that can be done without hampering the whole effort. Otherwise, these guidelines would apply to directors of adult transplant programs that can coordinate the pediatric transplant program.

13. Requirements for Intestine Transplant Programs. The Committee reviewed a draft document from the ASTS that set forth established criteria for ASTS Program Accreditation in Intestine Transplantation (**Exhibit R**). The Committee agreed this was a good starting point for establishing intestine transplant program criteria within the Bylaws.

The Committee also reviewed a memo from the MPSC requesting input on the activity level for intestinal transplant programs, as well as information about the Committee's efforts to establish criteria for intestinal transplant programs. Currently, the only requirement for an intestine program is that the center must have an approved liver program. When a transplant center wants to perform intestine transplants, it must submit a letter to the Membership Department, complete a staffing survey indicating the key staff members, and establish a UNetSM site administrator for the program. The Membership Department will then report to the MPSC that the program has initiated the process. UNOS certifies programs, not individuals within each program.

The ASTS requires that 10 intestinal transplants must be performed annually for two years. If an individual has completed a fellowship in a program that meets these requirements, he or she would be eligible to serve as the director of an intestine program. If the Committee plans to parallel the fellowship requirements of the ASTS recommendations in its own recommendations, there should be

additional pathways that would accommodate those individuals that have on-the-job experience or who trained prior to when the ASTS requirements were applicable. The Committee was reminded that one of the main reasons the criteria proposed several years ago did not move forward was that they were seen as too restrictive.

The Committee proposed the following criteria:

- Training at an ASTS-approved fellowship (in programs that perform at least 10 intestine transplants in 2 years in addition to 5 procurements)
- Completion of a liver transplant fellowship followed by an additional year of training in intestinal transplantation at an ASTS-approved program.
- Experience pathway - Perform 10 intestine transplants and 5 procurements as primary surgeon or first assistant over a 2-5 year period in order to get conditional approval. Perform 15 intestine transplants and 5 procurements as primary surgeon or first assistant over a 2-5 year period in order to get full approval.
- Must be a liver transplant surgeon.

The Committee also discussed the requirements for the primary physician for an intestine transplant program. With intestine transplants, the medical management of intestinal transplant patients is extremely important, as there are issues with nutrition and gut rehabilitation that might require a multi-disciplinary team. A subcommittee will work out the details and further address these complicated issues. Data should be provided to support the rationale for the number of procedure and patient care requirements.

14. Memorandum from MPSC Regarding Living Donor Liver Transplantation. The Committee reviewed a memorandum from the MPSC containing several questions raised following the MPSC's proposal to clarify the Bylaws related to conditional approval of live donor liver programs. The MPSC's questions and the Committee's responses are as follows:

- Is there a requirement that each program have at least two surgeons who meet the requirements for living donor hepatectomy? Should the level of experience required for approval as a qualified donor hepatectomy surgeon be the same for surgeons performing adult-to-adult lobar transplantation and those who perform only adult-to-pediatric segmental hepatic transplants?

The Committee agreed there was no reason to have two surgeons meeting the requirements for the left lateral segment procedure. Regarding the right lobe, Committee members stated that the rationale for this requirement was to make sure there would be two qualified surgeons available if there was a complication related to the donor and one surgeon was unavailable. The Committee recommended the following for adult-adult right lobe live donor procedure:

- One qualified live donor liver transplant surgeon (according to the Bylaws), and;
- A liver transplant surgeon or hepatobiliary surgeon practicing in a transplant center and performs at least 20 major liver resections per year.

- Is there a need to continue the requirement for programs that have received only conditional approval (due to the living donor hepatectomy inexperience of one of their surgeons), that “both of the designated surgeons must be present at the donor’s operative procedure?”

The Committee agreed that both surgeons should be present. If the changes proposed in the previous question are put in place, this conditional pathway will no longer be necessary.

- Are the most appropriate cases being used to demonstrate experience with liver surgery in both the full and conditional pathways? The bylaws currently state these surgeons must “have demonstrated experience as the primary surgeon or first assistant in 20 major hepatic resectional surgeries (to include living donor operations, splits, reductions, resections, etc), 7 of which must have been live donor procedures, within the prior 5-year period.”

The Committee agreed that “splits” should be removed from the bylaw requirements. The Committee also felt that CPT code 47399 “Unlisted liver procedure” should be removed.

- The MPSC recently approved changes in Bylaw language that would clarify that the living donor requirements apply only to programs performing the living donor surgery. These changes are intended to address the situation where the donor surgery is performed in an approved living donor liver center but the transplant is performed in a separate transplant center. The MPSC asked for the Committee’s input on this proposal in advance of it being submitted for public comment.

The Committee agreed that this is acceptable. However; if this change is specifically referring to cases when the donor procedure is performed at an adult transplant center and the transplant is performed at the pediatric center, then it needs to be clear in the bylaw language. The Committee agreed that language should be added for clarification, especially with kidney paired donation potentially becoming more commonplace.

- This bylaw change noted in the preceding paragraph could conceivably result in a circumstance where the surgeon performing the living donor liver transplant had relatively little or no experience with living donor hepatectomy. Should we establish separate experience thresholds for surgeons who perform the living donor liver transplant itself, perhaps incorporating experience accrued in the transplantation of deceased donor liver segments or reduced grafts?

The Committee did not feel that requirements should be created for surgeons that are performing the recipient procedure.

- Should liver transplant programs that perform living donor hepatectomy and/or transplants be reviewed for functional inactivity in the living donor portion of the program specifically and, if so, what metrics should be used to initiate review of the programs?

The Committee agreed that it is important to set some minimum activity level for living donor hepatectomy/transplants. Due to the small volume at most centers, the Committee

agreed that if you do not perform at least one living donor transplant within a one year period, the MPSC will review the program.

The input from these discussions will be provided to the MPSC and be taken under advisement for a joint subcommittee of the MPSC/Liver/Pediatric/Living Donor.

15. Status 1A/1B Review Subcommittee. The Subcommittee had reviewed 35 Status 1A/1B cases reviewed (26 1A and 9 1B). The Subcommittee agreed that 17 (48.6%) were appropriate and 12 (34.3%) were inappropriate. Of the remaining cases, the Subcommittee will request more information on three cases (8.6%) and another three will require a Subcommittee conference call. For cases deemed inappropriate, the center will either get a letter of inquiry, a letter of initial “warning” or referral to MPSC depending on whether the center has had previous referrals. UNOS staff is reviewing the past record of programs with inappropriate cases.
16. OPO Committee Request for Input. The Committee reviewed a memorandum from the OPO Committee requesting input on the definition of multi-system organ failure. The Committee agreed that this was difficult to define but formed a subcommittee to further discuss the issue. During the March 2009 meeting, subcommittee members noted that this work was in process.
17. ABO Incompatible Liver Transplants. Under current policy, with the exception of candidates listed at a Status 1A or Status 1B, livers from blood type O donors may only be offered to blood type O or blood type B candidates with a MELD or PELD score of at least 30. However there are situations, especially with the younger liver candidates, where a donor liver from any blood type could be used. A member requested that the Committee consider changing the allocation policy for ABO compatibility so it is similar to what is in heart allocation. The Committee requested data that would provide the number of ABO incompatible liver transplants being done as well as the patient and graft survival rates for these recipients.
18. Candidates with Atypical Hemolytic Uremic Syndrome (aHUS). The Committee reviewed a letter from a member requesting that the Committee consider expanding the criteria for adult liver transplant for candidates with aHUS. The letter also included a consensus manuscript about the use of liver transplants for this condition as well as a letter from some international experts on aHUS supporting a possible policy change. The Committee agreed that, due to the relatively small number of cases, these should be handled by the RRB, possibly requiring a conference call in order to further inform the RRB of the condition and the need for exception points.
19. ASTS Living Donor Liver Transplant Training Proposal. The Committee discussed a proposal by the ASTS and American Association for the Study of Liver Diseases (AASLD) for a scholarship to sponsor a surgeon to obtain hands-on experience overseas (“Traveling Surgical Scholarship in Living Donor Liver Transplantation”). It is difficult to receive training in the U.S. for adult-to-adult living donor transplantation. However, in some countries a surgeon can scrub in as first assistant in these cases, enabling surgeons to gain first-hand experience that they cannot get in the U.S. The Committee was asked to consider whether this training would meet the criteria for a living donor transplant surgeon. The current policy does not mention international training. A Subcommittee will review this pathway and recommend whether it should be endorsed as a training mechanism, and/or whether some guidelines should be developed to ensure that the training is appropriate.
20. Guidance for Developing Program-Specific Living Liver Donor Medical Evaluation Protocols. The Living Donor Committee asked that the Liver Committee provide comment on this proposal prior to it being circulated for public comment. The Committee had no comments during the March 2009 meeting, and Committee members were requested to provide feedback via e-mail.

21. Memorandum Regarding Status 1 Candidates with HBV. The Committee reviewed a memorandum from DEQ regarding candidates with fulminant hepatic failure who have a diagnosis of hepatitis B and are listed as a Status 1A. The Committee was asked if it is appropriate for the transplant center to select “no pre-existing liver disease” on the justification form and include the information in the narrative, or whether these candidates should not be listed as Status 1A. Members discussed candidates with acute-on-chronic hepatitis B, versus non-cirrhotics with an acute flare-up who behave more like fulminants. The Committee agreed that the center should include the specifics of the candidate’s condition in the narrative; these would then be reviewed by the Status 1A/1B Subcommittee as is done currently. In the near future, the retrospective review function will be moved back to the RRBs, with oversight from the Subcommittee and full Committee. This will bring the process back into alignment with policy approved several years ago, and will provide more timely feedback to the centers.

22. “Amnesty” for Status 2A/2B Justification Forms. The Committee was informed that there are 2,965 outstanding liver status 2A/2B Justification forms. Since these forms were eliminated in 2002, the Committee felt that the forms should not be considered expected or delinquent (17 in favor, 0 opposed, 0 abstentions).

**ATTENDANCE AT THE NOVEMBER 19, 2008
OPTN/UNOS LIVER AND INTESTINAL ORGAN TRANSPLANTATION COMMITTEE
Chicago, IL**

Committee Members	Position	In Attendance
Elizabeth A, Pomfret, M.D., Ph.D.	Chair	Yes
W Kenneth Washburn, M.D.	Vice-Chair	Yes
Heung Bae Kim, M.D.	Region 1 Representative	Yes
David Reich, M.D., FACS	Region 2 Representative	Yes
Nigel Girgrah, M.D., Ph.D.	Region 3 Representative	Yes
Luis Mieles, M.D.	Region 4 Representative	Yes
David Douglas, M.D.	Region 5 Representative	Yes
John M Ham, M.D.	Region 6 Representative	Yes
Julie K Heimbach, M.D.	Region 7 Representative	Yes
Surendra Shenoy, M.D., Ph.D.	Region 8 Representative	Yes
Thomas D Schiano, M.D.	Region 9 Representative	No
Shawn J Pelletier, M.D.	Region 10 Representative	No
James D Eason, M.D.	Region 11 Representative	Yes
Scott Biggins, M.D.	At-Large	Yes
Patricia L Carroll, PA-C, CPTC	At-Large	Yes
Richard C Johnson, Ph.D.	At-Large	Yes
Steven Lobritto, M.D.	At-Large	Yes
Lisa McMurdo, RN, MPH	At-Large	Yes
Don C Rockey, M.D.	At-Large	Yes
J C Rosenberg, M.D., Ph.D.	At-Large	No
Janel N Tedesco, ACNP, CCTC	At-Large	No
Kerri Wahl, M.D.	At-Large	Yes
Bernard Kozlovsky, M.D., M.S.	Ex-Officio, HRSA	No
Monica Lin, Ph.D.	Ex-Officio, HRSA	Yes
UNOS Staff		
Erick B Edwards, Ph.D.	Asst. Dir., Research Dept.	Yes
Ann Harper	Committee Liaison/Policy Analyst	Yes
Robert Hunter	Committee Liaison/Policy Analyst	Yes
Arbor Research Staff		
Robert Merion, M.D.	Clinical Transplant Director	Yes
Mary Guidinger, M.S.	Analytic Staff	Yes
Doug Schaubel, Ph.D.	Biostatistician	Yes

**ATTENDANCE AT THE MARCH 31, 2009
OPTN/UNOS LIVER AND INTESTINAL ORGAN TRANSPLANTATION COMMITTEE
Chicago, IL**

Committee Members	Position	In Attendance
Elizabeth A, Pomfret, M.D., Ph.D.	Chair	Yes
W Kenneth Washburn, M.D.	Vice-Chair	Yes
Heung Bae Kim, M.D.	Region 1 Representative	Yes
David Reich, M.D., FACS	Region 2 Representative	Yes
Nigel Girgrah, M.D., Ph.D.	Region 3 Representative	Yes
Luis Mieles, M.D.	Region 4 Representative	No
David Douglas, M.D.	Region 5 Representative	Yes
John M Ham, M.D.	Region 6 Representative	Yes
Julie K Heimbach, M.D.	Region 7 Representative	Yes
Surendra Shenoy, M.D., Ph.D.	Region 8 Representative	Yes
Thomas D Schiano, M.D.	Region 9 Representative	Yes
Shawn J Pelletier, M.D.	Region 10 Representative	Yes
James D Eason, M.D.	Region 11 Representative	Via Telephone
Scott Biggins, M.D.	At-Large	Yes
Patricia L Carroll, PA-C, CPTC	At-Large	Via Telephone
Richard C Johnson, Ph.D.	At-Large	No
Steven Lobritto, M.D.	At-Large	Yes
Lisa McMurdo, RN, MPH	At-Large	Yes
Don C Rockey, M.D.	At-Large	Yes
J C Rosenberg, M.D., Ph.D.	At-Large	Yes
Janel N Tedesco, ACNP, CCTC	At-Large	Yes
Kerri Wahl, M.D.	At-Large	Yes
Bernard Kozlovsky, M.D., M.S.	Ex-Officio, HRSA	Yes
Monica Lin, Ph.D.	Ex-Officio, HRSA	Yes
UNOS Staff		
Erick B Edwards, Ph.D.	Asst. Dir., Research Dept.	Yes
Ann Harper	Committee Liaison/Policy Analyst	Yes
Arbor Research Staff		
Robert Merion, M.D.	President / Clinical Transplant Director	Yes
Mary Guidinger, M.S.	Analytic Staff	Yes
Doug Schaubel, Ph.D.	Biostatistician	Yes
Guests		
Susan Mandell, M.D., Ph.D.	University of Colorado Hospital	Yes
Charles Miller, M.D.	Cleveland Clinic	Yes
Jennifer Dorrell, M.S.	Ohio Solid Organ Transplantation Consortium	Yes
Sara O'Loughlin, MHA, FACHE	Univ. Wisconsin Transplant	Yes

**ATTENDANCE FOR THE MAY 14, 2009
OPTN/UNOS LIVER AND INTESTINAL ORGAN TRANSPLANTATION COMMITTEE
Conference Call**

Committee Members	Position	In Attendance
Elizabeth A, Pomfret, M.D., Ph.D.	Chair	Yes
W Kenneth Washburn, M.D.	Vice-Chair	Yes
Heung Bae Kim, M.D.	Region 1 Representative	No
David Reich, M.D., FACS	Region 2 Representative	Yes
Nigel Girgrah, M.D., Ph.D.	Region 3 Representative	No
Luis Mieles, M.D.	Region 4 Representative	No
David Douglas, M.D.	Region 5 Representative	Yes
John M Ham, M.D.	Region 6 Representative	Yes
Julie K Heimbach, M.D.	Region 7 Representative	Yes
Surendra Shenoy, M.D., Ph.D.	Region 8 Representative	No
Thomas D Schiano, M.D.	Region 9 Representative	No
Shawn J Pelletier, M.D.	Region 10 Representative	Yes
James D Eason, M.D.	Region 11 Representative	Yes
Scott Biggins, M.D.	At-Large	No
Patricia L Carroll, PA-C, CPTC	At-Large	Yes
Richard C Johnson, Ph.D.	At-Large	No
Steven Lobritto, M.D.	At-Large	No
Lisa McMurdo, RN, MPH	At-Large	Yes
Don C Rockey, M.D.	At-Large	No
J C Rosenberg, M.D., Ph.D.	At-Large	No
Janel N Tedesco, ACNP, CCTC	At-Large	Yes
Kerri Wahl, M.D.	At-Large	No
Bernard Kozlovsky, M.D., M.S.	Ex-Officio, HRSA	Yes
Monica Lin, Ph.D.	Ex-Officio, HRSA	Yes
UNOS Staff		
Erick B Edwards, Ph.D.	Asst. Dir., Research Dept.	Yes
Ann Harper	Committee Liaison/Policy Analyst	Yes
Bob Metzger	Medical Director	Yes
Arbor Research Staff		
Mary Guidinger, M.S.	Analytic Staff	Yes
Doug Schaubel, Ph.D.	Biostatistician	Yes
Guests		
Rich Durbin	HRSA	Yes
James Bowman	HRSA	Yes
Robert Walsh	HRSA	Yes