

OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Report to the Board of Directors
November 14-15, 2011
Atlanta, GA

Summary

I. Action Items for Board Consideration

- The Board is asked to approve modifications to Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) that more clearly define the imaging characteristics of HCC (Item 1, Page 3).
- The Board is asked to approve modifications to Policy 3.6 (Adult Donor Liver Allocation Algorithm) that provide broader access to deceased donor organs for candidates awaiting a combined liver-intestine transplant (Item 2, Page 5).
- The Board is asked to approve a Committee-sponsored alternative allocation system for split liver allocation that would allow a transplant center that accepts a right lobe for transplantation into a candidate on its list to transplant the left lobe/left-lateral segment into any other medically suitable listed patient at that institution or an affiliated pediatric institution (Item 3, Page 6).

II. Other Significant Items

- The Committee submitted two proposals for public comment in September 2011 for potential submission to the Board in June 2012; (1) an extension of the current “Share 15 Regional” policy that would offer deceased donor livers (age 18 and higher) to all candidates with MELD/PELD scores of 15 or higher locally, regionally, and nationally before being offered to candidates with lower MELD/PELD scores and (2) a proposal that would offer livers to all local and regional candidates in Status 1A or 1B, and those with MELD/PELD scores of 35 or higher, before candidates with lower MELD/PELD scores (Item 4, Page 7).
- The Committee is considering enhancements to the MELD score, including the addition of serum sodium (Item 5, Page 9).
- The Committee is investigating ways to reduce liver discards, and to facilitate expedited placement of livers not accepted at the local or regional level (Item 6, Page 9).

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Kim M. Olthoff, M.D., Chair
David C. Mulligan, M.D., Vice Chair

This report presents the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee's (Liver Committee) deliberations during its July 21, 2011, meeting and June 6, 2011, conference call.

1. Proposal for Improved Imaging for Hepatocellular Carcinoma (HCC). Patients awaiting a liver transplant who are diagnosed with HCC are eligible for additional priority through MELD/PELD exceptions. Currently, HCC exceptions are based on diagnostic criteria that rely on imaging characteristics rather than liver biopsy. The attendees of a multi-disciplinary HCC Consensus Conference held in November 2008 made specific recommendations regarding the appropriate imaging criteria to properly determine HCC staging. The Committee surveyed all liver programs (n=132) in the U.S. in October 2010 to determine acceptance of these recommendations. The Committee received 77 responses to the imaging survey. Eighty-six percent supported a change that would more clearly define the imaging characteristics of HCC, and 92% supported a policy requiring images used for documentation of HCC to be performed at the transplant center or be reviewed by a multi-disciplinary team at the transplant center. Ninety percent of respondents reported that the imaging specifications are similar to what is currently being used at their transplant centers. Using the consensus conference working group's recommendations for imaging classification and minimum technical specifications for MRI and CT as guidance, the Committee has developed a proposal that incorporates these recommendations into OPTN policy. Key changes to the policy are as follows, with specific details of the proposal provided in **(Exhibit A)**.
 - As in current policy, only patients within Milan criteria (Stage T2) are eligible for an automatic HCC exception. In the proposed policy, Stage T2 is defined as:
 - 1 lesion ≥ 2 cm and ≤ 5 cm, OR 2-3 lesions, all ≥ 1 cm and ≤ 3 cm in size.
 - Lesions less than 1cm are indeterminate, and will not count towards the overall staging of HCC for automatic priority.
 - Stage T1 HCC would no longer be eligible for automatic priority, regardless of the AFP level.
 - A more precise classification scheme for liver nodules is also proposed. OPTN "Class 5" lesions meet all diagnostic criteria for HCC and are eligible to be considered for automatic HCC MELD exception.
 - Smaller lesions (1-2 cm) must meet more stringent imaging criteria than larger lesions (2-5cm) in order to be diagnosed as HCC on multiphase contrast enhanced imaging (CT or MRI) and qualify for automatic priority. Candidates will still be required to have more than one (may have two or three) smaller lesions to meet T2 criteria and qualify for MELD exception points.

- Lesions between 1-2 cm must be hypervascular on arterial phase imaging, and demonstrate portal vein/delayed phase washout **and** pseudocapsule enhancement. If both wash-out and pseudocapsule enhancement are not present, they must demonstrate growth on serial imaging.
- Lesions between 2-5 cm must be hypervascular on arterial phase imaging and demonstrate portal vein/delayed phase washout or pseudocapsule enhancement. If no wash-out or pseudocapsule enhancement, lesion must demonstrate growth on serial imaging.
- Lesions less than 1 cm are indeterminate (and thus, not eligible to be considered as HCC).
- Liver imaging with multiphase contrast enhanced imaging (CT or MRI) must be performed or interpreted at a transplant center, and should meet minimum technical standards as described in Tables 4 and 5 of the policy.

The proposal was circulated for public comment in March 2011. Of the 32 individual comments received, 69% with an opinion (n=26) were in support of the proposal. All regions except Region 4 were in support of the proposal. Only the Patient Affairs Committee voted on the proposal, with a vote of support. ASTS and NATCO indicated their support. Comments in opposition to the proposal were mostly related to additional costs and data burden. However, the proposal should not increase costs or data burden, except for the requirement for outside scans to be repeated at the transplant center. No additional data submission is required, and an optional template is provided for ease of documentation. Further, a survey of all programs in 2010 indicated that more than 70% of images are already being read or performed at the transplant center, and 90% of respondents indicated that the requirements in the proposal were similar to what they are currently doing. There were some concerns about how UNOS would monitor the minimum technical standards in Table 4 and 5; however, these were recommended as guidelines, not requirements. The proposal will be amended to clarify that Tables 4 and 5 are recommended, but not required.

The American College of Radiology's LI-RADS (Liver Imaging - Reporting and Data System) Committee, which has developed a similar but not identical classification system for HCC imaging, sent a letter opposing the proposal as written. The LI-RADS criteria are tailored for diagnosis of HCC, while the proposed OPTN policy criteria are tailored for identifying candidates with HCC who are eligible for automatic exception points for liver transplantation. The current proposal described OPTN Class 0-5, but only Classes 0 (incomplete or technically inadequate study) and 5 (meets radiologic criteria for HCC) are relevant to the policy, while 1-4 are diagnostic. The subtle differences between the OPTN proposal and the LI-RADS recommendations were resolved via a conference call on July 20, 2011. As a compromise, the policy will be modified to reflect only OPTN classes 0 and 5, and Table 6 will be simplified to remove differences between the two systems, with a reference to the LI-RADS website. The Committee submits the following for consideration by the Board of Directors:

***** RESOLVED, that Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) shall be amended as set forth in Exhibit A, effective pending notification and programming in UNetSM.**

Committee Vote: 21 in favor, 1 opposed, and 3 abstentions.

The Resource and Impact Statement for this proposal is provided in (**Exhibit B**).

2. Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates. In June 2009, the Committee received a letter from several intestine transplant surgeons noting the high waiting list mortality for these candidates. The letter cited several studies as evidence that the waiting list death rate is highest for intestine candidates as compared to other organs, and that the adult death rates were nearly double that of their pediatric counterparts. The letter contained several suggestions for change, including additional priority and increased access. The Committee requested an updated analysis of the waiting list mortality for adult liver-alone versus liver-intestine candidates. In July 2009, the Intestine Issues Working Group was formed, and charged with “reviewing the request for change to the adult liver-intestine allocation algorithm and developing evidence-based recommendations for the committee to consider.”

Data provided to the Committee demonstrated an increased mortality risk for adult liver-intestine candidates relative to those awaiting a liver alone. The Working Group suggested that the allocation sequence be altered such that these candidates would have broad access to livers. Several Committee members expressed concerns about the potential impact of such a change on short-statured adults waiting for a liver alone, who compete for the same donor pool. Data presented to the Committee indicated that, while small-statured liver-alone candidates have a slightly higher risk of waiting list mortality than taller candidates (RR=1.12), candidates awaiting a liver-intestine transplant experience nearly a three-fold increase (RR=2.78). After reviewing the analyses, and discussing the need for increased access for these patients regardless of the allocation priority provided, the working group recommended that the adult donor algorithm be modified such that livers would be offered to combined liver-intestine candidates *nationally* if there are no Regional Status 1A/1B candidates, or local candidates with a MELD/PELD score of 29 or higher. This would be restricted to candidates with short-gut syndrome (SGS), at least initially, due to the inconsistency in practice across existing transplant centers and lack of established/accepted indications or criteria for liver-intestine transplantation in this group of patients. The proposed adult donor liver allocation algorithm is shown in Table 1. The Committee is not proposing changes to the MELD/PELD scores currently assigned to these candidates at this time.

The proposal was circulated for public comment in March 2011. Of the 25 individual comments received, 83% with an opinion (n=18) were in support of the proposal. Regions 1,4,5,6, and 11 were in support of the proposal, and Region 2 supported it with amendment. Regions 3, 7, 8, 9, and 10 did not support the proposal. The Organ Availability and Pediatric Committees supported the proposal while the Patient Affairs Committee did not. ASTS and NATCO indicated their support. Comments in opposition to the proposal included (Committee responses in italics):

- Why not award more points to adults? *This is already in place; adults listed for a liver and intestine currently receive a score equivalent to a 10 percentage point increase in their mortality risk.*
- There should be a floor for the MELD score assigned to the patients. *Currently with the 10 percentage point increase, the lowest MELD score that is assigned is 20.*
- Will adversely impact small-statured adult. *This was addressed in proposal; these candidates have an elevated risk of waiting list mortality, but not nearly as high as those waiting for a liver-intestine.*
- What about the poor post-transplant outcomes? *Data presented at the 2011 American Transplant Congress showed that there is still a net benefit to transplanting these patients due to their high waiting list mortality (391 deaths per 1000 patient-years at risk). Post-transplant mortality rates*

fall to 142 deaths per 1000 patient-years at risk, about a 64% reduction. This is similar to the reduction in mortality for adult liver-alone candidates (136 deaths per 1000 patient-years at risk on the waiting list to 55 deaths per 1000 patient-years following transplant, a 60% reduction).

Table 1. Proposed Adult Donor Liver Allocation Algorithm

1	Combined Local and Regional Status 1A candidates in descending point order
2	Combined Local and Regional Status 1B candidates in descending point order
3	Local Candidates with MELD/PELD Scores ≥ 15 29 in descending order of mortality risk scores
4	National Liver-Intestine Candidates in descending order of mortality risk scores
5	Local Candidates with MELD/PELD Scores 15-28 in descending order of mortality risk scores
6	Regional Candidates with MELD/PELD Scores ≥ 15 in descending order of mortality risk scores
7	Local Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores
8	Regional Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores
9	National Status 1A candidates in descending point order
10	National Status 1B candidates in descending point order
11	National All other candidates in descending order of mortality risk scores

The Committee agreed to forward the proposal to the Board of Directors, and plans to review the impact of the proposal two years after implementation, especially the effect on small statured adults. The Committee submits the following for consideration by the Board of Directors:

***** RESOLVED, that Policy 3.6 (Adult Donor Liver Allocation Algorithm) shall be amended as set forth in (Exhibit C), effective pending notification and programming in UNetSM.**

Committee Vote: 21 in favor, 1 opposed, and 1 abstention.

The Resource and Impact Statement for this proposal is provided in **(Exhibit D)**.

3. Committee Sponsored AAS for Split Liver Allocation. During the November 2010 meeting, the Board of Directors approved the Region 2 and OneLegacy Split Liver AASs, which had been circulated for public comment in the spring of 2010. Under these AASs, if an adult/adolescent candidate is offered a liver through the standard policy (i.e., via the match run) and has been determined to be suitable for a segmental liver transplant (known as the index patient), the candidate's transplant center may transplant the right lobe into that index patient. The center may then transplant the left lobe/left-lateral segment into any other medically suitable listed patient at that institution or an affiliated pediatric institution (if applicable). After approving these AASs, the Board directed the Committee to pursue a committee-sponsored AAS (CAS) for split livers. In December 2010, the Committee voted to develop a CAS for split liver allocation based on the Region 2 and OneLegacy proposals, by a vote of 14 in favor, 0 opposed, 0 abstentions.

The proposal was circulated for public comment in March 2011. Of the 24 individual comments received, 100% with an opinion (n=17) were in support of the proposal. All regions were in support of the proposal. The OPO, Patient Affairs, and Transplant Coordinators Committees supported the proposal. The Pediatric Transplantation Committee did not support the proposal, for the same reasons the Committee did not support the Region 2 and OneLegacy AASs upon which this was modeled. ASTS and NATCO indicated their support. The Committee will follow up with the Pediatric Committee to determine if there are issues that can be resolved. The Committee voted to forward the proposal to the Board by a vote of 23 in favor, 0 opposed, and 1 abstention. If approved, a plan will

be developed to advertise this and to enroll participants. The Committee submits the following for consideration by the Board of Directors:

***** RESOLVED, that new Policy 3.6.12 (Committee-sponsored Alternative Allocation System (CAS) for Segmental Liver Transplantation), replacing Policy 3.6.12 (Transition of Currently Listed Candidates), shall be approved as set forth in (Exhibit E), effective pending notification to the membership.**

Committee Vote: 23 in favor, 0 opposed, and 1 abstention.

The Resource and Impact Statement for this proposal is provided in **Exhibit F**.

4. Ongoing Policy Development for Broader Distribution of Livers. During the June 2011 conference call and July 2011 meeting, the Committee reviewed the results of 18 separate LSAM models, including the current policy (**Exhibit G**). These included the “Share 15 National” (Share15N) and “Share 35 Regional” (Share35R) and “Share 32 Regional” (Share32R) concepts. Share35R and Share32R were modeled with sharing thresholds (STs) of 3, 2, 1, and 0, alone and in combination with Share15N. For each of these, the Committee reviewed the:

- Decrease in total deaths vs. percent shared;
- Decrease in waitlist deaths vs. percent shared;
- Decrease in total deaths vs. median distance;
- Death rate vs. median distance; and
- Percent of liver transplants benefit from the sharing thresholds system among all transplants.

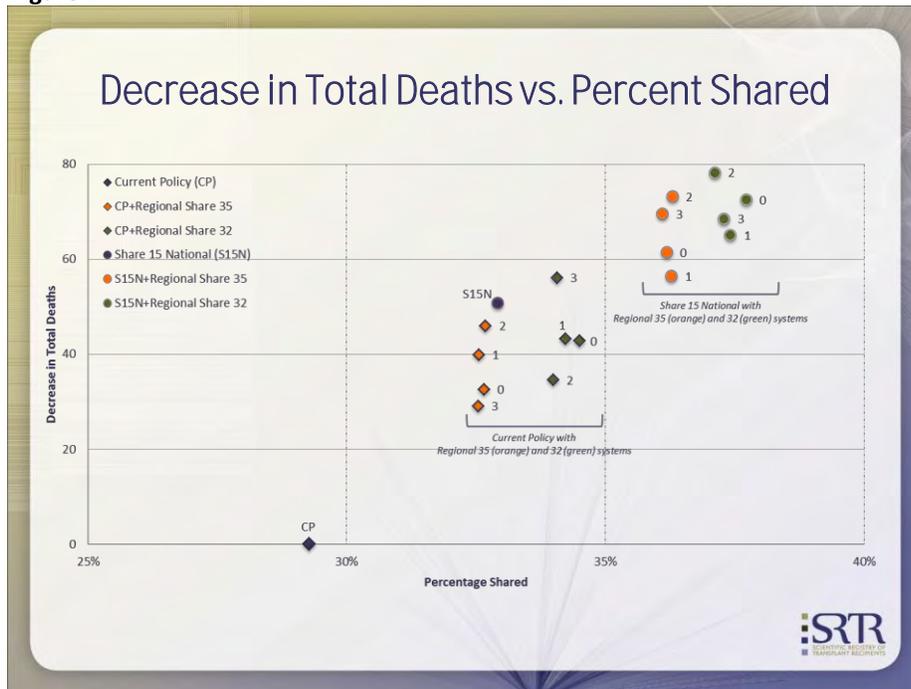
The greatest decreases in total deaths (70-80 per year) resulted from the combined Share15N /Share 35R (with STs 0-3), followed by the Share15N alone, and then the Regional sharing scenarios (**Figure 1**). The reduction in waiting list deaths was significant ($p= 0.001$) for the Share 15N/Share 35R combination but the change in total deaths was not statistically significant. Most of the benefit was derived from the Share15N, with most of the decreases in total deaths due to decreases in waiting list deaths. The impact of the various sharing thresholds (0,1,2,3) is indeterminate, as the number affected by the threshold is small (approximately 5% across all proposals). There were minimal increases in the median distance an organ traveled across the proposals modeled.

During the July 2011 meeting, the Committee reviewed a letter (**Exhibit H**) from Kathleen Sebelius, MPA, Secretary of the U.S. Department of Health and Human Services, requesting that “the OPTN develop one or more variances to demonstrate the efficacy of broader distribution of livers with the goal of reducing intertransplant program variation on appropriate clinical endpoints such as mortality on the waitlist and MELD at time of transplant.” Any variance must be in accordance with the Final Rule and OPTN policies. Further, any variance approved by the OPTN must “be designed in a scientific manner with the goal of demonstrating the impact of broader distribution policy options on clear end-points (e.g., reduced mortality of candidates on the waiting list.)” The Committee reviewed the evidence gathered to support the Share 15 National and Share 35 regional proposals. In addition to the LSAM modeling, the Committee cited analyses indicating that candidates with MELD scores of 35-40 have mortality rates similar to those in Status 1, and Regional Status 1 distribution has been in place since December 2010. Further, there has been a large reduction in waiting list deaths since

Share 15 Regional was implemented in August 2005. The Committee feels that Share 15 has been well-demonstrated in all 11 regions since that time.

HRSA representatives in attendance described this as a request from the Secretary for the OPTN to take a more proactive approach within the context of the requirements of the OPTN Final Rule and the directive and guidance HHS received from Congress in the 2010 conference report. The conference report lists a number of requirements that must be met before the OPTN can implement any changes to the liver distribution policy. One of the key requirements is that a proposal must be designed to show reasonable efficacy that can be demonstrated before implemented nationally. The letter further articulated the constraints that the OPTN is under by direction of Congress. The letter does not stipulate statistical significance, because sometimes that is not possible to achieve. It was further noted that the language was limited to broader distribution, and so would not apply to a change in the MELD score, for example. The Committee could revise the definition of Status 1 to include Candidates listed with a MELD score of 35 and above, based on the mortality data cited. This would be a change to allocation and not distribution and thus not subject to the requirements of the report language.

Figure 1



The Committee discussed each proposal separately. Based on the evidence described earlier, the Committee approved a motion to circulate the Share 15 National proposal for public comment by a vote of 23 in favor, 0 opposed, and 1 abstention.

The Committee discussed whether the proposal for a Regional Share 35 with a sharing threshold of 3 should move forward. A motion to do so was made and seconded. Committee members discussed the need for a sharing threshold, which adds complexity, but would have a very small impact based on the modeling results. The sharing threshold may make people comfortable that livers will not be crossing in the air for similarly ill patients, which also adds to cost.

The Committee discussed the notion of a change to the definition of Status 1. This would accomplish the same goal with the same patient population. The Committee reviewed the death rates for these candidates, which are significantly higher than candidates with lower scores. Committee members were concerned that altering the definition of Status 1 would not be supported by the community. The current Status 1 definition typically includes patients who have sudden onset of disease and do well with a transplant, while the patients with MELD scores of 35 or higher, while equally sick, are usually chronically ill patients who do not do as well. Thus, while the mortality risk is similar, the candidates are not similar in terms of outcomes. However, Committee members also felt they should heed the advice they had been given. The category could be called “Status 1 MELD” and possibly include a sharing threshold. The motion for Regional Share 35 was withdrawn after discussion.

A new motion was made to create a Status 1 MELD category for those candidates with calculated MELD scores of 35 and higher. This category would fall after the Status 1As and 1Bs. The model that most closely represents this concept is the Share 35 with a ST of 0. Under this model, organs are offered by MELD score, with local always before regional at each score. The Committee agreed with the sequence as modeled. This motion was approved by a vote of 22 in favor, 1 opposed, and 1 abstention.

The Committee discussed whether Status 1MELD should include exceptions. The motion approved would apply to calculated MELD scores only, while the modeling data reviewed included exceptions. Some of the exceptions in this category are those with HAT that receive a MELD exception score of 40. It was noted that most candidates with exceptions are transplanted before reaching a MELD score of 35, and that those cases could be reviewed by the Status 1 Review Subcommittee. A new motion to consider including all candidates with MELD/PELD scores of 35 or higher was made and seconded. This motion was approved by a vote of 22 in favor, 2 opposed, and 1 abstention. The public comment proposal will ask specifically whether exceptions should be included.

After the July Committee meeting, discussions about the “Status 1MELD” proposal during Policy Oversight and Executive Committee conference calls led Committee leadership to revert back to the original proposal for a “Share35R” rather than Status1MELD, although both proposals are based on the same algorithm. Both proposals were circulated for public comment in September 2011 (**Exhibits I and J**).

Subcommittee Updates

5. MELD Enhancements and Exceptions Subcommittee. The Subcommittee requested that the Scientific Registry of Transplant Recipients (SRTR) contractor update the MELD-Na analysis that had been published in the New England Journal of Medicine (NEJM). The revised results were similar to those published in the NEJM, with updated lower and upper bounds for sodium of 125 and 137 mmol/L (**Exhibit K**). There is an 8% increased risk of death per unit decrease in serum sodium concentration between 137 and 125 mmol/L (RR = 1.08, 95% CI 1.07-1.09, p<0.001). The effect of serum sodium is greater in candidates with lower MELD scores. The SRTR is currently working on requests to refit the current MELD equation, the MELD-Na equation, and to assess the impacts of each using both.
6. Liver Utilization Working Group. During the July meeting, the Committee received a brief update on the efforts of the Liver Utilization Working Group. This Working Group has been reviewing data in order to identify factors related to expedited placement and has also identified a subset of expedited placements that occurred between specific OPO/center combinations (**Exhibit L**). The Working Group has been collaborating with the Effective Screening Work Group to identify centers that routinely turn down offers for certain types of donors, despite acceptance criteria indicating the center

would accept such offers. This analysis has been performed for kidney transplant programs, and letters were sent to kidney programs to encourage centers to use realistic acceptance criteria.

7. Status 1 Review Subcommittee. During the July meeting, the Committee reviewed the new process for review of Status 1 cases that do not meet the criteria in policy, which has been in place since August 2010. Status 1A and 1B cases that do not meet criteria are reviewed by the Status 1 Subcommittee soon after listing. Reviews and votes are conducted using the UNetSM Committee Management System. If a listing is found to be inappropriate by a majority vote, the center is given the option to downgrade the patient, appeal the decision and provide more information, or keep the candidate at the status (with referral to the Liver Committee and possibly the Membership and Professional Standards Committee). In some instances, centers choose to ask the Subcommittee to vote prior to listing the patient (i.e., prospective review). Between November 2010 and May 2011, 27 candidates were listed who did not meet criteria. Of those, only one was transplanted in that status.
8. Re-execution of the Match System Subcommittee. In 2010, The Department of Evaluation and Quality (DEQ) asked the Committee to better define when re-execution of the liver match is appropriate. The current policy allows for re-execution if there is a „change in specific medical information related to the liver donor,‘ which is not well-defined. The Subcommittee is revising the policy language, as much of it is outdated. The Subcommittee has asked for the reasons the match has been re-executed in the past, to make sure that it considers all reasonable situations. If this is not possible, the Subcommittee requests that DEQ keep a list of the reasons moving forward.

Review of Items Circulated for Public Comment, March-June 2011

9. Items Circulated for Public Comment by other Committees, March 2011. The Committee reviewed five proposals that had been circulated for public comment.
 - A. Proposal to Improve Reporting of Living Donor Status (Living Donor Committee). This proposal would require centers to “report an accurate and timely patient status (alive or dead) for at least 90% of their living donors at the required post-operative reporting periods (6, 12, and 24 months).” Timely is defined as within 60 days of the required reporting dates. If approved, the policy would apply only to new living donors, and would not be retrospectively applied. The Committee approved this by a vote of 15 in favor, 0 opposed, 0 abstentions.
 - B. Proposal to Improve the Packaging and Shipping Requirements of Living Donor Organs, Vessels and Tissue Typing Materials (Living Donor Committee). This proposal would bring the policies for packaging, labeling and shipping living donor organs in line with those for deceased donor organs. The policies for deceased donors are currently more stringent than those for living donor organs. The proposed policy would only apply to organs that are shipped outside the recovery center. Transplant centers would maintain responsibility for the packaging, labeling, and shipping of living donor organs to transplant centers, but could enter into an agreement with an OPO to coordinate those functions. The Committee approved this by a vote of 15 in favor, 0 opposed, 0 abstentions.
 - C. Proposal to Require Confirmatory Subtyping of Non-A₁ and Non-A₁B Donors (Operations and Safety Committee). Donors with non-A₁ (often called A₂) and A₁B blood type are sometimes transplanted into recipients with other blood types. The requirement for double verification of donor blood type does not currently apply to subtypes. This may lead to inaccurate donor blood type information being entered, potentially causing graft loss. It is estimated the double verification of subtyping would reduce the error rate from 3.5% to 0.032%. It was reported that the OPO community has some mixed feelings about this, as a number of hospitals do not have the

ability to perform subtyping. One member noted that if the A₂ subtype cannot be independently verified then the donor should be listed as an A₁; this is what currently happens per OPTN policy. The Committee approved this by a vote of 14 in favor, 0 opposed, 1 abstention.

D. Proposal to Standardize Label Requirements for Vessel Storage and Vessel Transport (Organ Procurement Organization (OPO) Committee). The proposed policy would:

- Eliminate the requirement to place a label on the rigid container for vessel storage;
- Make the policy requirements for labeling vessel storage consistent with those for vessel transport;
- Clarify that vessels be stored in a triple sterile barrier labeled with the UNOS distributed label; and
- Change the “CDC Guidelines” to the “Public Health Service Guidelines.”

The Committee approved this by a vote of 14 in favor, 0 opposed, 0 abstentions.

E. Proposal to Update and Clarify Language in the DCD Model Elements (Organ Procurement Organization (OPO) and Organ Availability Committees). The proposed changes to the Donation after Cardiac Death (DCD) Model Elements would update and clarify language regarding DCD, and update the bylaws so they will be current with accepted practice. The Committee noted that the proposal should be amended to apply to both Medicare and non-Medicare hospitals, so that all transplant programs are subject to the same standards. The Committee approved this by a vote of 14 in favor, 0 opposed, 0 abstentions.

F. Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B and Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital’s Intensive Care Unit to Qualify as Status 1A or 1B (Pediatric Transplantation Committee). The Committee has already endorsed these two proposals and continues to do so.

Other Updates

10. Approved Committee Projects. During its June 2011 meeting, the Executive Committee approved eight projects (new and ongoing) that the Committee will be working on in 2011-2012:

- Further development of policies to reduce geographic disparities in waiting list mortality;
- Ongoing review of MELD/PELD exceptions;
- Additional priority for DCD recipients that require retransplant;
- Facilitated placement / reduced discards;
- Enhancements to the MELD score / liver allocation;
- Ongoing review of Status 1A/B cases not meeting criteria;
- Allocation of livers for hepatocyte transplants; and

- Intestinal surgeon/physician criteria.

11. LSAM Modeling Tutorial. The SRTR provided an overview of the LSAM model, including the primary components, input data and probability model. The current model uses the actual candidate and donor population from 2006, as developed by Arbor Research. Organ acceptance and post-transplant survival rates are estimated. Thus, the model is a mixture of fixed and simulated elements. The Committee reviewed the covariates included in the organ acceptance models for Status 1A and Status 1B/MELD/PELD candidates. The SRTR is in the process of updating the model with more recent data. The SRTR is also planning enhancements to the model that will allow simulation of potential behavioral changes that could result from a policy change (e.g., candidate listing or organ acceptance practices), and will collaborate with the Committee when making these refinements.
12. Member Request Regarding Allocation of Hepatocytes. Currently, hepatocytes are allocated based on Policy 3.6.10 (Allocation of Livers for Other Methods of Hepatic Support), which states that:

“A liver shall not be utilized for other methods of hepatic support prior to being offered first for transplantation. Prior to being utilized for other methods of hepatic support, the liver shall be offered by the Organ Center in descending point order to all Status 1 A and 1B candidates, followed by all candidates in order of their MELD/PELD scores (probability of candidate death) in the Host OPO's region followed by Status 1 A and 1B candidates, and then by all candidates in order of the MELD PELD scores probability of candidate death) in all other regions. If the liver is not accepted for transplantation within 6 hours of attempted placement by the Organ Center, the Organ Center shall offer the liver to Status 1 A and 1B, followed by all candidates in order of their MELD/PELD scores (probability of candidate death) for whom the liver will be considered for other methods of hepatic support. Livers allocated for other methods of hepatic support shall be offered first locally, then regionally, and then nationally in descending point order to transplant candidates designated for other methods of hepatic support.”

Thus, offers must be made to the entire list of whole and/or split liver candidates before being offered to those willing to accept hepatocytes. A member requested that the Committee reconsider this policy, and stated that the hepatocytes are being used to treat pediatric patients with acute liver failure and liver-based metabolic disorders.

When this was discussed in June, Committee members felt that the transplantation of hepatocytes has not been generally accepted as standard practice, and that the current allocation sequence for hepatocytes is sufficient. However, the topic was brought to the Committee again in July, and the Committee agreed to work with the OPO Committee to further address this issue, as there may be an opportunity to educate the OPOs about the current policy. Centers with these listings will also be contacted to ensure that they are being listed appropriately.

13. Reporting of Life Support on Tiedi® Forms. The Committee was asked to clarify what forms of life support are appropriate to include on the life support “other specify” text field on the liver Transplant Recipient Registration (TRR) form. A review of these data included responses such as oxygen, dialysis, TPN, etc. This variable is included in the program-specific reports generated by the SRTR. There are a number of other risk adjustment factors in the PSRs that are also subjective, such as previous abdominal surgery and portal vein thrombosis. The Committee would like to review these fields and provide definitions and instruction for the members. It will be important to have clear definitions for these variables as the Committee continues to study the net benefit concept.

Committee Participation
Liver and Intestinal Organ Transplantation Committee
Conference Call, June 6, 2011
Attendance

W. Kenneth Washburn, MD	Chair	X
Kim Olthoff, MD	Vice Chair	X
Michael Curry, MD	Regional Rep. Region 1	X
Stephen Dunn, MD	Regional Rep. Region 2	
Brendan McGuire, MD	Regional Rep. Region 3	X
Goran Klintmalm, MD, PhD	Regional Rep. Region 4	X
Ryutaro Hirose, MD	Regional Rep. Region 5	X
Jorge D. Reyes, MD	Regional Rep. Region 6	X
Anthony D'Alessandro, MD	Regional Rep. Region 7	
Harvey Solomon, MD	Regional Rep. Region 8	
Lewis Teperman, MD	Regional Rep. Region 9	X
John Fung, MD, PhD	Regional Rep. Region 10	X
Michael Marvin, MD	Regional Rep. Region 11	X
Scott Biggins, MD	At Large	X
Julie Heimbach, MD	At Large	X
Heung Bae Kim, MD	At Large	
Timothy McCashland, MD	At Large	
Kenyon Murphy, JD	At Large	
John Roberts, MD	At Large	X
Debra Sudan, MD	At Large	X
Kim Brown, MD	At Large	X
Kareem Abu-Elmagd, MD	At Large	
Michael Charlton, MD	At Large	
James Trotter, MD	At Large	X
Thomas Mone	At Large	X
James Eason, MD	At Large	
James Bowman, MD	Ex Officio, HRSA	X
Monica Lin, PhD	Ex Officio, HRSA	X
Ba Lin, PhD	Ex Officio, HRSA	X
Peter Stock, MD	MMRF, SRTR Representative	X
Yi Peng, MS	MMRF, SRTR Representative	X
Jon Snyder, PhD	MMRF, SRTR Representative	X
Jiannong Liu, PhD	MMRF, SRTR Representative	X
Taqee Khaled, MPH	MMRF, SRTR Representative	X
Erick Edwards, PhD	UNOS, Assistant Director of Research	X
Ann Harper	UNOS, Policy Analyst	X
Cheryl Hall	UNOS, Business Analyst	X
Jory Parker	UNOS, Business Analyst	X

**Committee Participation
July 21, 2011**

Kim Olthoff, MD	Chair	X
David C. Mulligan, MD	Vice Chair	X
Shimul A. Shah, MD	Regional Rep. Region 1	X
Andrew Cameron, MD	Regional Rep. Region 2	X
Brendan McGuire, MD	Regional Rep. Region 3	X
Mark R. Ghobrial, MD, PhD	Regional Rep. Region 4	X
Johnny C. Hong, MD	Regional Rep. Region 5	X
Jorge D. Reyes, MD	Regional Rep. Region 6	By phone
David C. Cronin, II, MD, PhD	Regional Rep. Region 7	X
Michael D. Voigt, MB, ChB	Regional Rep. Region 8	X
Lewis Teperman, MD	Regional Rep. Region 9	By phone
John Fung, MD, PhD	Regional Rep. Region 10	X
Michael Marvin, MD	Regional Rep. Region 11	X
Tom Mone	At Large	X
Kim Brown, MD	At Large	X
Kareem Abu-Elmagd, MD	At Large	X
Michael Charlton, MD	At Large	By phone
James Trotter, MD	At Large	X
James Eason, MD	At Large	X
Simon P. Horslen, MB, ChB	At Large	
Goran B. Klintmalm, MD,	At Large	X
Thomas Starr	At Large	X
Fredric G. Regenstein, MD	At Large	X
Srinath Chinnakotla, MD	At Large	X
Ryutaro Hirose, MD	At Large	By phone
Julie Heimbach MD	At Large	X
James Bowman, MD	Ex Officio, HRSA	X
Richard Durbin	Ex Officio, HRSA	By phone
Monica Lin, PhD	Ex Officio, HRSA	By phone
Ba Lin, PhD	Ex Officio, HRSA	By Phone
Peter Stock, MD	MMRF, SRTR Representative	X
Yi Peng, MS	MMRF, SRTR Representative	X
Jon Snyder, MD	MMRF, SRTR Representative	By phone
W. Ray Kim, MD	MMRF, SRTR Representative	By phone
Bertram Kasisky, MD	MMRF, SRTR Representative	By phone
Maureen McBride, PhD	UNOS, Director of Research	By phone
Erick Edwards, PhD	UNOS, Assistant Director of	X
Ann Harper	UNOS, Policy Analyst	X
Lee Goodman	UNOS IT Department	X