

Liver and Intestinal Organ Transplantation Committee
March 15, 2012
Chicago, IL
INTERIM REPORT

1. Review of Share 15 National Proposal. The proposal was circulated for public comment on September 16, 2011 and comments closed on December 23, 2011. Of the 42 individual comments received, 76% (n=28) of those with an opinion (n=37) were in support of the proposal. All 11 regions were in support of the proposal. Four Committees voted on the proposal (Patient Affairs, Pediatric Transplantation, Transplant Administrators and Transplant Coordinators) and all were in support. AST, ASTS and NATCO indicated their support. Comments in opposition to the proposal were mostly related to concerns about increased costs and cold ischemia time, and the threshold of 15 being based on old analyses. A group representing patients with congenital hepatic fibrosis felt that these patients would be disadvantaged by Share 15 and requested that the Committee develop an exception for this diagnosis. The Committee voted unanimously to forward this to the Board for consideration in June 2012.
2. Review of Share 35 Regional Proposal. The Committee reviewed public comments received for the Share 35 Regional proposal. The proposal was circulated for public comment on September 16, 2011 and comments closed on December 23, 2011. Of the 44 individual comments received, 67% (n=39) of those with an opinion (n=26) were in support of the proposal. Five regions (55%) were in support of the proposal as written, three (27%) indicated support if amended. Two Regions were opposed and one Region had a tie vote. Four Committees voted on the proposal (Patient Affairs, Pediatric Transplantation, Transplant Administrators and Transplant Coordinators) and all were in support. AST, ASTS and NATCO indicated their support.

General comments in opposition to the proposal were mostly related to concerns about increased costs and cold ischemia time, and the potential effect on small programs. Many specific comments were related to:

- Inclusion of exceptions
- Inclusion of candidates awaiting a combined liver-kidney transplant
- Use of a “sharing threshold”

For each of these options, some regions were in support (e.g., exceptions must be included) while others were in opposition (e.g., exceptions must be excluded). As with the Share 15 proposal, a group representing patients with congenital hepatic fibrosis felt that these patients would be disadvantaged by Share 15 and requested that the Committee develop an exception for this diagnosis. Several commenters felt that offers should not be made by descending MELD score, but rather to candidates with score of 35 and higher as a group.

The Committee reviewed data requested for this meeting related to the Share 35 proposal. The Committee had asked for a tabulation of the number of candidates waiting on the list with a MELD/PELD score of 35 or higher, as well as how many were ever waiting with a score of 35 or higher during a fixed time period, and how many were transplanted with such scores. The Committee asked that the data be stratified by diagnosis, adult versus pediatric, and whether the candidate had a MELD/PELD exception.

The cohort of candidates on the list as of October 1, 2010 plus those candidates added to the list between October 1, 2010 and September 30, 2011, was used for the analysis of candidates ever waiting. Candidates were categorized based on the highest score or status reached. For the analysis of the number of candidates waiting at any point in time, the waiting list “snapshot” as of November 30, 2011 was used. Finally, the transplant analyses included liver transplants occurring between October 1, 2010

and September 30, 2011. Those candidates who had MELD score of 35 and higher but were also listed in Status 1 at some point were counted as Status 1s. Those patients whose MELD score was a result of a combined liver-intestine listing were also shown. Analyses were also stratified by Region. These analyses are summarized as follows:

Table 1 Data Requested for Share 35 Proposal

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| <ul style="list-style-type: none"> ▪ MELD/PELD 35+ represent:0.6% of snapshot candidates <ul style="list-style-type: none"> – Region 2, 5, 7 (56% of adults) – Region 2 (82% of pediatrics) – Non-cholestatic cirrhosis (59% of adults) – Biliary atresia + metabolic (50% of pediatrics) – Exception (19% of adults; 93% of pediatrics) – Non-standard exceptions (77% of pediatrics; 62% of adults) • 7.8% of candidates ever waiting during a year <ul style="list-style-type: none"> – Region 5 (n=606;30% of adults) Regions 2,5,7,9 (64% of adults) – Region 2 (n=70; 38% of pediatrics) – Non-cholestatic cirrhosis (70% of adults) – Biliary atresia + Metabolic (39% of pediatrics) – Exception (9.7% of adults; 49% of pediatrics) – Liver-intestine (< 1% of adults; 16% of pediatrics) – HCC + HAT (64% of adults) – Non-standard (84% of pediatrics; 30% of adults) • 18.6% of deceased donor transplants in a year <ul style="list-style-type: none"> – Majority are adults in each region; Region 5 had most (31% of US total) – Region 2 had most pediatrics (28% of US total) – Non-cholestatic cirrhosis (67% of adults) – Biliary atresia/Metabolic (53% of pediatrics) – M/P 35+ by exception points (5.9% of adults) – M/P 35+ by exception points (73% of pediatrics) – Hepatic artery thrombosis (53% of adults) – Non-standard exceptions (85% of pediatrics; 32% of adults) |
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The majority of adults had a diagnosis of non-cholestatic cirrhosis, whereas the majority of pediatric candidates were listed with biliary atresia or metabolic diseases. Most pediatric patients with MELD/PELD score of 35 and higher had an exception, and most had non-standard exceptions.

The Committee discussed whether exceptions should be included. Several regions indicated support if the proposal was limited to calculated MELD scores only. One Committee member felt that it would be difficult to explain to patients with an exception why they were excluded from the regional sharing pool while others were included. Committee members noted that candidates with exceptions represent a small number of those with MELD scores 35 and higher, so inclusion of exceptions is likely to have small impact. Further, the standard exceptions for adults (e.g., HAT) are most likely to reach scores of 35 or higher. The Committee approved a motion to include all exceptions by a vote of 20 in favor, 2 opposed, and 1 abstention.

The Committee discussed inclusion of a Sharing Threshold (ST). Previous simulation modeling had showed that the ST does not make much of an impact, affecting 5% of transplants. One Committee member noted that the only area of the country that may be affected is Hawaii (and Hawaii noted the need for a variance to this proposal). In Region 9, which shares for all MELD scores across a wide area,

increased cold ischemia time is not a problem. It was noted that human behavior often dictates CIT, i.e., whether the surgeon allows another team to procure the organ, when the OR is scheduled, etc. The Committee approved a motion that there should be no sharing threshold, by a vote of 20 in favor, 2 opposed, and 1 abstention.

Regarding inclusion of candidates awaiting a combined kidney-liver transplant, an initial motion that these should be excluded was made and seconded. Some Committee members argued that these are the some of the sickest candidates and so should be included. Several regions were opposed to the inclusion of combined kidney-liver candidates. Region 8 recommended that there should be a payback for kidney -liver transplants occurring under Share 35, but Committee members noted that paybacks are generally not desirable and have been phased out for liver allocation. The Committee will reconvene by conference call to reconsider inclusion of these candidates pending review of additional data listed in Table 2.

In its public comment response, the Pediatric Transplantation Committee asked how PELD scores would be handled, as they often range above a score of 40. The Committee felt that PELD scores would be ranked from highest to lowest by score, like the MELD score, with local candidates being raked above regional candidates at each score.

Table 2. Additional Data Requested for Share 35 Regional Proposal

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| Provide measures of waiting list survival and post-transplant survival for the following groups: a. All MELD/PELD 35+ candidates b. MELD/PELD 35+ candidates with exceptions c. MELD/PELD 35+ candidates without exceptions d. MELD/PELD 35+ candidates by special category: i. MELD/PELD 35+ liver candidates not on renal replacement therapy ii. MELD/PELD 35+ liver candidates on renal replacement therapy iii. MELD/PELD 35+ liver-kidney candidates |
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3. HCC Subcommittee Report. The Committee reviewed the slides to be presented during the Spring 2012 Regional meetings for the “HCC Hold” proposal. Committee members asked that the slides include the potential benefit of using “HCC Hold” to liver programs, which include:
- It will eliminate offers for high-MELD patients that the center is not yet ready to transplant;
 - Improves efficiency of the system (fewer turndowns);
 - Decreases required applications for extensions, and tests required to complete applications;
 - Allows centers to utilize different ways of treating these patients (e.g., TACE, RFA), while providing the safety net of transplant if/when tumor recurs or demonstrates growth

The proposal will also serve as a way to educate centers that they can already inactivate a candidate with an exception; however the center must resubmit extensions every three months, and the score will keep increasing while inactive.

The Committee was also notified that the explant pathology form has been programmed and is awaiting approval by the Office of Management and Budget (OMB), but can be implemented very soon after OMB approval.

Potential Changes to HCC Allocation

The Committee reviewed an analysis of “dropout rates” for HCC candidates by region, compared to rates for non-HCC candidates. Waiting list “dropout” is defined as being removed from the waiting list for death (either member-reported to the OPTN or identified using the SSDMF) or for the reason of “too sick.” The analysis included candidates added to the waiting list between July 1, 2008 and June 30, 2011. Those with exceptions for Stage T1 HCC were excluded, as were candidates listed in Status 1 and pediatric candidates. For those without HCC exceptions, candidates who had an exception at some point in time or a diagnosis of cancer were also excluded. Candidates were also included in the “drop-out” group if they were removed for a reason of “other” and the required ‘reason for removal’ text field indicated that the removal was HCC-related. The probabilities for transplant or death within one year of candidate listing were estimated using competing risks methodology. Candidates with HCC exceptions entered the analysis on the date of the first approved application.

The final study cohort included 4,515 with standard HCC exceptions, 1,237 with HCC exceptions not meeting the policy criteria, and 19,649 non-HCC/non-exception registrations. The dropout rates within 12 months for HCC were 13.9% (range among regions 4.8% - 21.7%) versus 17.7% for non-HCC (range among regions 12% - 23.2%). The confidence intervals did not overlap, so the rates were statistically significant; it was noted that multivariable analyses have also shown statistical significance. The rates for those with HCC exceptions not meeting criteria were based on very small numbers and should be considered in that context. Transplant rates showed similar variations.

Committee members noted that in some regions with longer waiting times (e.g., Region 5), the dropout rates for HCC exceptions over time may be higher than the non-exception candidates. Thus, it may be useful to analyze rates over a longer period of time (i.e., 18 to 24 months). Committee members asked that the numbers associated with the calculated percentages be displayed on the graphs, and that the candidates with HCC not meeting criteria be removed.

The HCC Subcommittee has been exploring different ways to assign priority to candidates with HCC. The participants of the HCC Consensus Conference held in November 2008 recommended a continuous allocation score that would be based on the MELD score and tumor characteristics (e.g., size and number of tumors, tumor growth, alpha-fetoprotein (AFP)) to reflect the biology of HCC. The Subcommittee had expressed concerns about the score, specifically the use of AFP, which would likely negatively impact post-transplant outcomes. The Subcommittee asked that the score be modeled several ways (e.g., removing the AFP) to see how the use of a score would impact transplant and dropout rates.

The greatest disparity between HCC and non-exception candidates was seen between regions where candidates wait a very long time versus those that wait only a few months before receiving a transplant. The Subcommittee is also considering a possible requirement that candidates must wait for some period of time (e.g., 3 or 6 months) before being eligible to receive a MELD exception score for HCC. While waiting, candidates could still receive offers based on the calculated MELD score. Committee members felt that requiring a waiting period would help equalize the dropout rates between HCCs and non-exceptions in some regions, and has biologic validity. Another option being considered is to set the initial exception score based on the median MELD score at transplant in each region. This could possibly improve access for sick candidates without HCC exceptions. Exception scores could be reduced for the initial score assignment, and also capped at some level. However, reducing the score could be harmful to candidates in some regions where the waiting times to transplant are longer. After discussion, Committee members agreed that the continuous score should not be investigated at this time, but that

other options should be pursued. The Committee also asked for an update of an analysis of HCC recurrence that had been provided several years ago.

4. MELD Exceptions and Enhancements Subcommittee Report. This Subcommittee has been working with the SRTR to improve the accuracy of the MELD score. The SRTR has investigated updating the MELD equation parameters (“Refit MELD”), adding serum sodium (MELD-Na), and combination of the two (Refit MELD-Na). The Committee reviewed analysis of four models; each model was compared to the current MELD score:
 1. Refit the current MELD equation using recent OPTN/SRTR data to assess changes in the MELD coefficients.
 2. Refit the MELD-Na equation using the Refit MELD equation as a starting point, holding the Refit MELD coefficients fixed (Refit MELD-Na -1)
 3. Refit the MELD-Na equation allowing refitting of all MELD coefficients with the inclusion of serum sodium (Refit MELD-Na -2)
 4. Add sodium to the current MELD equation (MELD-Na)

The analyses included all candidates who added to the liver transplant waiting list between January 1, 2007 and December 31, 2010, excluding candidates younger than 12 years of age, those with a previous liver transplant, candidates listed as Status 1, and those with a history of malignancies. Data for candidates added to the list in 2009-2010 were used to refit MELD /MELD-Na equation; data from those added in 2007-2008 registrants were used to validate the refit equation. The components of the current MELD score (serum bilirubin, serum creatinine, INR) plus serum sodium (all from the time of waitlist registration) were used for refitting MELD/MELD-Na.

The Committee reviewed the distributions of each of the covariates used to identify outliers and to determine the optimal cut-points for each covariate. Under the refit model, the bilirubin would have upper and lower bounds of 1 and 19 mg/dL; creatinine would have upper and lower bounds of 0.7 and 3.2 mg/dL; and INR from 0.9-5.2. The current formula sets lower bounds for each component of 1. The validation analyses showed that the refit score is a better fit in terms of the relative risk of death.

The second set of analyses replicated the first request, but with the addition of serum sodium. Per the request, the equations were recalculated with all components (including serum sodium) refitted. The optimal cut-points are as follows:

- Bilirubin: 1-29 mg/dL
- Creatinine: 0.8-3.6 mg/dL
- INR: 0.9-5.2
- Sodium: 126-139 mmol/liter

All five models (MELD, MELD-Na, Refit MELD, Refit MELD-Na-1, and Refit MELD-Na-2) were then compared based on *discrimination* (the ability to rank patients according to their risk of death) as well as *calibration* (the ability to estimate the exact probability of death). For the purposes of ranking for organ allocation, discrimination is more important to consider than calibration. In terms of discrimination, the c-statistics ranged from 0.868 (current MELD score) to 0.88 (Refit MELD-NA 1). All the confidence limits overlapped, indicating that none of the models seem to be markedly superior to the other. In terms of calibration, the all of the models yielded results that were close to the observed value for low MELD values. For higher ranges of MELD scores (30+) the Refit MELD-Na models were the closest to the observed value.

Each version of the MELD score was modeled using LSAM, which has been updated to 2010 data. Prior LSAM analyses using data from 2006 had predicted 59 fewer waiting list deaths with MELD-Na over the

current MELD score. Using the updated LSAM, Refit MELD-NA 1 resulted in the greatest reduction in total deaths (-61.3). Transplant volume was predicted to increase, presumably because the scores are on average higher, and the acceptance model would lead to more candidates accepting organs than with their current scores. A summary of the results is shown in Table 3.

Table 3 SRTR MELD Refit Analyses

| | MELD-Na | Refit MELD | Refit MELDNa 1 | Refit MELDNa 2 |
|---|----------------|-------------------|-----------------------|-----------------------|
| Discrimination: C-statistic | 0.877 | 0.872 | 0.880 | 0.879 |
| Calibration: Sum Squared Errors Sum of | 264 | 188 | 109 | 98 |
| LSAM | | | | |
| Pre-Tx Deaths | -66 | -27 | -57 | -47 |
| Post-Tx Deaths | +15 | +1 | -4 | +3 |

Committee members discussed whether the revised score would significantly re-order the list, with candidates who have poor renal function getting less priority and those with cholestatic disease getting more priority, based on the changes to the coefficients (i.e., decreasing the coefficient for creatinine and increasing for bilirubin). The revised score would also change the MELD thresholds in place (and proposed) in policy; for example, the refit MELD score of 15 would mean something different clinically than the current score. The Committee requested an analysis of the impact of the revised scores on various diagnostic groups.

Based on these data, the Subcommittee recommended that the Committee adopt the MELD-Na score. That model is simple, more accurate than the current MELD, and is predicted to save 50 lives each year. There was no numeric advantage to using the refit MELD. The Subcommittee felt that concerns about gaming the system and increased costs associated with serum sodium were not valid, as current factors in the MELD score could be ‘gamed’ to the same extent that sodium might, and sodium data is already being collected. The concern that the addition of sodium will lead to poor patient care and poor post-transplant outcomes (due to central pontine myelinolysis) was also discussed. There was also some concern about the additional post-transplant deaths predicted by LSAM. There was consensus that the accuracy of the MELD score should be improved, and based on current data, but there was concern about the limited benefits and possible negative impacts of changing the score. The Committee will review additional data, specifically the impact of the revised scores by diagnostic group, prior to developing a policy proposal.

MELD Exceptions / Regional Review Boards

The MELD Exceptions and Enhancements Subcommittee has asked to review the outcomes (i.e., approved, denied) of MELD/PELD exceptions, by region. Concerns have been expressed that there is a conflict of interest in the RRB’s decisions, in that centers may approve cases with the hope that the RRB will in turn approve their cases. Further, some analyses have shown that there are inconsistencies in the reviews and case outcomes by Region, and the Subcommittee has been considering ways to make the RRBs more consistent and equitable. One possibility being explored is restructuring the review boards

so that some types of exception cases, perhaps the non-standard exceptions, would be sent to a review board made up of members from within the region and outside the region. However, some Committee members noted that each region is different in terms of the MELD scores at transplant and patient mix, and also felt that having representatives from within the region engenders trust in the process. There are also concerns about the lack of consistency in how RRB members are educated about the policies and process.

Transplant Benefit

The Committee has been discussing the topic of transplant benefit for several years. The prior SRTR contractor presented several analyses several years ago, including ‘benefit lite’ model that included only a few variables. There has been mixed acceptance by the transplant community. Committee members were asked to comment on whether to pursue transplant benefit. Response was mixed, with some strongly in favor and others strongly against. A net transplant benefit score may be unnecessary, as the MELD score was a strong component of the benefit models, post-transplant survival is relative high already, and there are mechanisms in place to reduce post-transplant deaths (such as MPSC review of outcomes). Further, studies have shown that the transplant center and/or the surgeon are strong factors in post-transplant outcomes, and those cannot be factored into a benefit score. It was noted that a benefit might be something to explore for pediatric patients, and may also be important if further broader sharing is pursued. No vote was taken.

Reconsideration of the PELD Score

The PELD score has not been revised since implementation in 2002. The Committee discussed the fact that half of the pediatric patients are listed in Status 1 or with an exception, which seems to indicate that the PELD score is not working as intended. A separate subcommittee will be formed to review the PELD score and options for improvement.

5. Liver Utilization Subcommittee Report. The Subcommittee had requested that the OPTN continue to refine an analysis of those donor characteristics that can define a donor profile suitable for expedited placement. The Subcommittee had seen several analyses that had not been presented to the full Committee. The most recent analysis was presented to the Committee. The study population included 14,601 adult donor livers recovered and transplanted between July 1, 2008 and June 30, 2011. Donors from Region 9 were excluded because this region already shares liver donors for all candidates, and would confound the results. Donors from Hawaii and Puerto Rico were also excluded due to the unique geography.

A “classification tree” analysis was used to identify subsets of donors that are more likely to be shared, using the following factors:

| | |
|--|--|
| • Age | • Causes of death |
| • Height | • Weight |
| • serum glutamic-oxaloacetic transaminase (SGOT) | • serum glutamic pyruvic transaminase (SGPT) |
| • Total bilirubin | • CDC high risk donor |
| • History of diabetes | • Ethnicity |
| • Split/Partial | • IV drug use |
| • Donation after circulatory death (DCD) | • Biopsy done |
| • Hepatitis B virus (HBV) | • Hepatitis C virus (HCV) |

The classification tree analysis is an exploratory technique that is useful for identifying combinations of variables that are associated with the outcome (in this case, donor livers being shared outside the local area). The software program splits the data recursively to identify those subsets with the most statistically significant differences in outcome. All factors were entered into the analysis at the start. The Subcommittee had recommended including the percentage of microvesicular/macrovesicular fat, but these data were too incomplete to include in the analysis. Of the total, 3394 (23.2%) were shared outside of the local area. The key factors that were identified as prevalent in donor livers that were shared were donor age, whole versus split/partial liver, HBV+, HCV+, and SGPT.

As shown in Figure 1, 65% of donors age 77 or older were shared. Data for the various combinations of these factors is shown in the figure. For example, 46% of those who were less than 77 years of age, with a biopsy, negative for HBV and HCV, and with an SGPT greater than 361 U/L. A total of 1,194 donors (8%) fit the donor profile. Those that fit the profile were shared outside the local area 48% of the time; those donors who did not fit the profile were shared 21% of the time. The odds ratio was 3.5. A total of 341 donors fitting the profile were discarded during the time period.

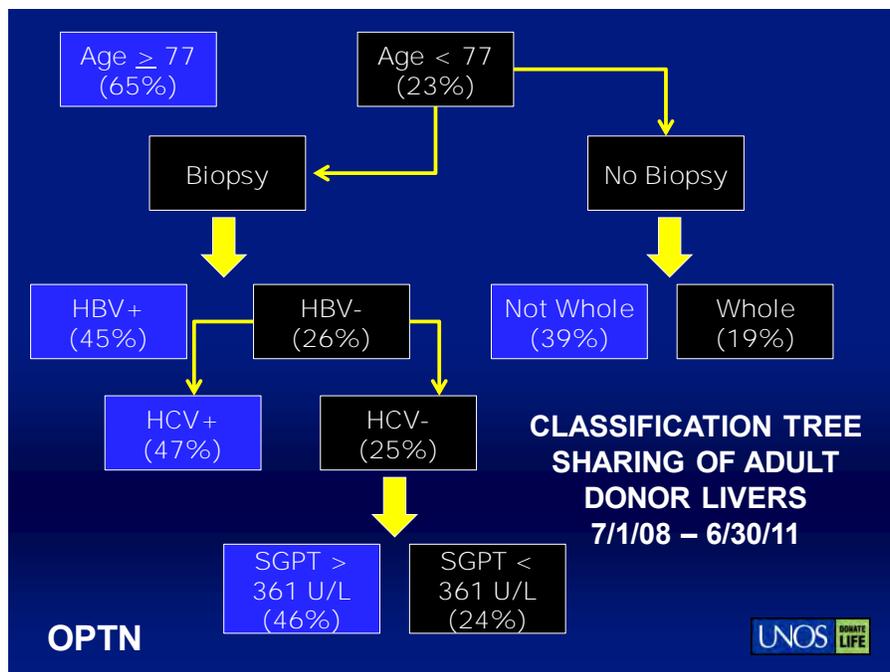


Figure 1

The Subcommittee’s goal is to reduce discards and to provide a more transparent system for expedited placement. The Subcommittee discussed proposing a regional share for donors meeting this profile, either by sending offers out to the whole region at once, based on the current allocation sequence, or creating a regional share (i.e., common pool) for these donors. A commonly stated concern about the current system is that centers within a region are being bypassed (i.e., are not getting organ offers) before an offer is made nationally, often to a specific transplant program. A previous analysis highlighted one OPO that exported livers to the same out-of-region center 13 times in 2009. OPOs in five states (PA, GA, NC, SC, and TN) accounted for almost 50% of the liver transplants that were done as a result of national shares.

The Subcommittee also desires to speed up the placement process for these types of donors. The time limit for centers to turn down offers could also be shortened, from one hour to perhaps 30 minutes. In DonorNet, offers can only be made to three centers at a time (pre-recovery; post-recovery donors can go out to five centers), which also slows down placement of these donors. Further, centers often turn

down these types of donors despite acceptance having criteria in UNet that would indicate a willingness to accept them. As part of its ongoing work in this area, the Effective Screening Working Group (ESWG) has already sent letters and a survey to 23 liver programs that consistently turn down offers for which there acceptance criteria indicate would be accepted.

The Subcommittee suggested that a separate waiting list could be created for these donors, and centers could opt in if they are willing to accept donors meeting the profile. This could be structured differently from the kidney expedited placement process, which allows centers to enter a 'provisional yes' and subsequently turn down organ after organ without any consequences. For example, centers that opt in would be held to some level of acceptance in order to remain on the list.

Committee members supported the concept of using a donor profile to expedite placement, and of increasing the number of centers that can receive offers at the same time. No action was taken.

6. Redistricting Regional Boundaries. The Committee received an update on this work from Dorry Segev, MD and Sommer Gentry, PhD; an initial overview was presented in December 2011. As described earlier, there is a trade-off between (1) decreasing deaths on the waiting list by regional sharing of livers and (2) increased the disparity in the mean MELD at transplant by DSA. The modeling seeks to determine if this trade-off could be eliminated using optimal redistricting with integer programming, by redistricting DSAs into regions by designing maps that combine DSAs into new regions. The LSAM can then be used to evaluate whether these new configurations can reduce geographic disparities in liver allocation. Two optimized maps were presented, one with 11 and one with 8 regions; in the second map, not all regions are contiguous. With this optimization technique, there was not necessarily a tradeoff between reducing deaths on waitlist and reducing disparity among DSAs. However, there will still be trade-offs associated with increased distance, as broader sharing always increases the distances organs travel. The researches posed several questions to the Committee:
- What types of regions are infeasible as liver distribution units?
 - Is there an upper limit of transport time in hours?
 - Are contiguous regions necessary?
 - Is some number of regions desired?
 - What tradeoffs should be made between increasing transport time and reducing deaths on waitlist / reducing disparities in access?

Studies have shown that cold ischemia time (CIT) is only weakly associated with distance, due mainly to factors that can be controlled by the surgeon or center. The only delay attributable to the distance is the transport time. The researchers are utilizing a database with geocoded locations of all donor hospital and transplant centers that will allow estimation of transport times using actual driving directions and airport to airport routes. The mode of transport (driving, helicopter, fixed wing) and associated times can be used in the model. Two OPOs are providing actual transport mode data to help validate the transport model. The model can calculate costs based on the type of transport. The Committee will continue to provide feedback as this work progresses.

7. Liver Biopsy Form and Resource Documents. The Organ Availability Committee (OAC) has developed a standardized liver biopsy reporting form and an accompanying resource document. These resources are designed for OPOs, who can make available to their pathologists. However, the OAC was dissolved in late 2011. The Liver Committee was asked to move these resources to the Board for approval, so that they can be published on the UNOS and OPTN websites. The Committee had reviewed these in December and was in favor of their use. The biopsy form would be voluntary (i.e., not a required form). The form is linked to a website with pictures that will help in reading the biopsies. The accompanying resource document provides a framework for standardizing biopsy photographs, including a ruler and

several views to show how photographs should be taken. The Committee discussed the statement in the document that says that pictures should not be sent via e-mail, for reasons of privacy (HIPPA). It was noted that deceased donors are exempt from HIPPA. However, the intent was to force these documents to be uploaded into DonorNet or other secure site, rather than e-mail or some other website; if this is the case, that should be made clear in the document. The Committee also suggested that a color wheel be included. The Committee approved a motion to forward these to the Board, with comments notes above, by a vote of 24 in favor, 0 opposed, and 0 abstentions.

8. Memo from OPO Committee Regarding: Hepatocytes. In 2011, a member asked the Committee for guidance regarding the allocation of hepatocytes. Currently, offers can be made to candidates listed for hepatocytes only after the list has been exhausted for whole organs. The Committee asked that the OPO Committee provide its perspective on this issue. In response, the OPO Committee opined that the only way to address the issue of hepatocyte allocation is to change the allocation policy itself, which the Committee has not been interested in doing. The originating issue seems to have been resolved somewhat by efforts to make sure that those candidates currently listed as willing to accept hepatocytes are listed appropriately. Several centers were contacted and many were found to be listed that way in error. This matter will be tabled unless there are additional inquiries.
9. Memorandum from the Policy Oversight Committee Seeking Input on Multi-Organ Allocation Policies. The Committee reviewed a memo from the POC asking for input on the following questions related to multi-organ allocation policies, specifically minimum listing criteria, policy ambiguities, ethical principles, and logistical issues:
 - 1) For those Committees with minimum listing criteria: Do you think the minimum listing criteria issues are resolved for your organ and if so, what are the important principles that were used to get there?
 - 2) Are there organ combinations for which minimum listing criteria do not exist but should?
 - 3) In order to minimize unnecessary multi-organ transplants, are there adjustments needed to the allocation system that will ensure a candidate who does not receive multiple organs (due to failure to meet minimal listing criteria) could get appropriate priority if subsequent to the transplant of the primary organ he/she develops failure of the second organ?
 - 4) Are there logistical issues regarding waiting list management surrounding multi-organ listing and transplant that need to be addressed?
 - 5) Are there procurement issues that could be addressed in this process?
 - 6) If the concept of lifesaving organ is removed, are there key ethical principles your Committee feels should be included in a framework for allocating the second organ based on a balance between equity and utility.

There are currently no minimal listing criteria for liver candidates. The Liver and Kidney Committees had developed criteria for liver-kidney candidates that were circulated for public comment, but the project was placed on hold because the logistics of implementing policies affecting two separate waiting lists were difficult. Committee members noted that patients listed for heart-liver transplants may get both organs when in fact the liver function may recover, making the liver transplant unnecessary. Committee members felt it will be important to look at outcome for these transplants. There have been many recommendations and guidelines from consensus conferences; the question is whether they should be made OPTN policy. A subcommittee will be formed to discuss this further and develop recommendations.

10. MELD/PELD Exception Cases Not Approved in 21 Days. Fourteen cases were referred to the Committee because an exceptional case application was not approved in 21 days, the center opted to keep the requested score, and the patient was transplanted at that unapproved score. All cases occurred in 2011.

Per policy, these are referred to the Liver Committee. Cases were reviewed by four Committee members. The reviewers noted several common themes: in many cases, the RRB members did not vote in a timely manner, or did not understand the policies. Committee members felt that RRB members should be reminded to respond in a timely fashion.

In a several cases, an appeal was submitted on the twenty-first day, so that the RRB did not have time to vote before the case is closed and the candidate can keep the score. This is a known “loophole” in the policy; however, there have been so few cases that it may not warrant re-programming the computer. There did not seem to be a pattern of behavior at any one center. It was noted that there were only 14 cases in 2011, and there was a mixture of RRB and center issues.

One issue with the RRBs is that there are many junior members serving on them, and there is no formal training. There should be more formalized training for RRB members. Committee member also discussed the composition of the RRBs, which are outlined in the RRB Operational Guidelines, which are approved by the Board. The composition of each RRB by Region will be provided to the Committee, as well as the Operation Guidelines, and any regional agreements for exception scores. The Committee will discuss this at the next meeting, and will develop some educational materials.

11. Protocols for Cholangiocarcinoma (CCA) Exceptions. The Committee ratified the CCA Subcommittee’s approval of protocols submitted by the Cleveland Clinic and University of Utah transplant programs.

Committee Participation, March 15, 2012

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| 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 | X |
| 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 | X |
| John Fung, MD, PhD | Regional Rep. Region 10 | X |
| Michael Marvin, MD | Regional Rep. Region 11 | X |
| Tom Mone | At Large | Via phone |
| Kim Brown, MD | At Large | X |
| Kareem Abu-Elmagd, MD | At Large | X |
| Michael Charlton, MD | At Large | X |
| James Trotter, MD | At Large | X |
| James Eason, MD | At Large | |
| Simon P. Horslen, MB, ChB | At Large | X |
| Goran B. Klintmalm, MD, PhD | 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 | X |
| Julie Heimbach MD | At Large | X |
| Ann Walia, MD | At Large | X |
| Ken Washburn, MD | At Large | |
| Ken Murphy | Board Liaison | |
| | | |
| James Bowman, MD | Ex Officio, HRSA | X |
| Monica Lin, PhD | Ex Officio, HRSA | Via phone |
| Ba Lin, PhD | Ex Officio, HRSA | Via phone |
| Jon Snyder, MD | MMRF, SRTR Representative | Via phone |
| Yi Peng, MS | MMRF, SRTR Representative | Via phone |
| Dorry Segev, MD | MMRF, SRTR Representative | Via phone |
| Sommer Gentry, PhD | MMRF, SRTR Representative | Via phone |
| Erick Edwards, PhD | UNOS, Assistant Director of Research | X |
| Ann Harper | UNOS, Policy Analyst | X |
| Manny Carwile | UNOS IT | X |