OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
<u>Amended</u> Report to the Board of Directors
November 8-9, 2010
St. Louis, MO

Summary

I. Action Items for Board Consideration

- The Board is asked to approve a request from LifeBanc of Ohio, Life Connection of Ohio and LifeCenter Organ Donor Network for a new Alternative Local Unit (ALU) in the State of Ohio. This would create a single waiting list within the ALU for liver allocation. The intent of the ALU is to allow for better, more efficient allocation of organs to those with the most urgent need on the waiting list over a larger geographic area (Item 1, Page 3).

- The Board is asked to approve a request from Region 2 for a Split Liver Alternative Allocation (AAS) System. The AAS would allow a center that accepts a liver offer for an adult candidate (the "index patient") to split the liver, using the right lobe in the index patient, and the left lateral segment in a pediatric candidate at that center or an affiliated pediatric center. The intent of this proposal is to increase the number of liver transplants by transplanting one donor liver into two recipients (Item 2, Page 4).

- The Board is asked to approve a request from OneLegacy for a Split Liver AAS. The AAS would allow a center that accepts a liver offer for an adult candidate (the "index patient") to split the liver, using the right lobe in the index patient, and the left lateral segment in a pediatric candidate at that center or an affiliated pediatric center. The intent of this proposal is to increase the number of liver transplants by transplanting one donor liver into two recipients (Item 2, Page 4).

- The Board is asked to approve a request to continue the Region 8 "Share 29" AAS until June 2011, pending review of more data (Item 3, Page 5).

II. Other Significant Items

- The Committee is planning to release a concept paper based on feedback from its 2009 Request for Information (RFI) on Liver Allocation and Distribution and the Forum on Concepts for Liver Allocation and Distribution held in April 2010 in Atlanta, GA. This will include several concepts that represent small, incremental improvements to the distribution of livers (Item 4, Page 7).

- The Intestine Issues Working Group is developing a proposal that would change the adult donor allocation sequence for liver-intestine candidates. These candidates have nearly three times the mortality rate than adult candidates waiting for a liver alone. The proposal would provide access to the national donor pool for these candidates if there are no local candidates

with a MELD/PELD score of 29 or higher, similar to the pediatric donor algorithm (Item 7, Page 11).

- The Hepatocellular Carcinoma (HCC) subcommittee has been developing recommendations for changes to Policy 3.6.4.4 (Liver Candidates with Hepatocellular Carcinoma (HCC)) based on the HCC Consensus conference held in November 2008. The Committee plans to survey all liver transplant programs in the fall of 2010 to assess the impact of potential proposed imaging requirements (Item 8, Page 13).

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

This report presents the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee's (Liver Committee) deliberations during its May 26, 2010, July 13, 2010, and September 7, 2010 conference calls. One additional item from the October 20, 2010 Committee meeting has also been included in this report.

I. Action Items for Board Consideration

Items Circulated for Public Comment, March 2010. The Committee sponsored three proposals that were circulated for public comment in March 2010. Each of these was an alternative allocation or distribution system requested by a Region, donation service area (DSA), or combination of DSAs.

1. Ohio Alternative Local Unit (ALU). Three DSAs in Ohio (LifeBanc, Life Connection of Ohio and LifeCenter Organ Donor Network) are requesting a new Alternative Local Unit. This would create a single waiting list within the ALU for liver allocation. The intent of the ALU is to allow for better, more efficient allocation of organs to those with the most urgent need on the waiting list over a larger geographic area. This is described in more detail in **Exhibit A**.

   The Committee reviewed the proposed Ohio ALU, as well as the comments received and the sponsoring parties' responses to those comments. The public comments received were 72% in support and 28% opposed. Regions 1, 2, 4, 5, 7, 9, 10, and 11 supported the proposal as written, while Region 8 supported the proposal with a proposed amendment. Regions 3 and 6 were opposed to the proposal. The Organ Procurement Organization (OPO), Organ Availability (OAC), Patient Affairs (PAC), and Transplant Coordinator (TCC) Committees were all in support, with no committees voting to oppose the proposal.

   Committee members felt that this proposal would create broader sharing of livers and a reduction in waiting list mortality. Simulation modeling of this proposal suggested that 26 organs per year would be allocated to sicker patients (i.e., with higher MELD/PELD scores) when compared to the standard national algorithm (i.e., with four local areas in Ohio). If all four DSAs were combined into a single list, the simulation modeling predicted that 37 more organs would be allocated to patients with higher MELD/PELD scores. Committee members expressed concern that the fourth DSA in Ohio was not included in the proposal. In their response to public comments, the three sponsoring parties stated that the fourth DSA and its liver transplant program "were invited to participate in forming a single statewide list. They declined to participate in this concept of broader sharing".

   Currently, there is an approved and implemented AAS with statewide sharing in Ohio that the OPTN/UNOS Board of Directors voted to dissolve in November 2009; this decision is currently

under review by the Secretary of Health and Human Services (HHS). It was reported that, if the new ALU proposal is approved by the Board, the appeal will be withdrawn in favor of the three-DSA single list. The Committee submits the following resolution for consideration by the Board of Directors:

**** RESOLVED, that the proposed Ohio ALU, as set forth in Exhibit A, shall be approved, effective pending notice and programming in UNet[SM].**

Committee vote: 15 in favor, 0 opposed, 0 abstentions.

The Resource and Impact Statement for this proposal is included as **Exhibit B**.

2. Region 2 and OneLegacy Split Liver Alternative Allocation Systems. Two proposals for split liver allocation were submitted for public comment in March 2010. Each would allow a center that accepts a liver offer for an adult candidate (the "index patient") to split the liver, using the right lobe in the index patient, and the left lateral segment in a pediatric candidate at that center or an affiliated pediatric center. The intent of these proposals is to increase the number of liver transplants by transplanting one donor liver into two recipients. Under current policy, a center that chooses to split a liver must offer the remaining segment to the local list rather than to candidates waiting on its own list. This has been seen as a disincentive to split liver transplantation. A complete description of the Region 2 proposal can be found in **Exhibit C,** and the Resource and Impact Statement can be found in **Exhibit D**. A complete description of the OneLegacy proposal can be found in **Exhibit E,** and the Resource and Impact Statement can be found in **Exhibit F**.

   Public comments received for the Region 2 proposal were 91% in support, with 9% opposed. Regions 1, 2, 3, 4, 6, 7, 9, 10, and 11 supported the proposal as written, with Region 8 in support of an amended proposal and Region 5 opposed. The following committees were in support of the Region 2 proposal: Operations (with condition), OPO, PAC, and TCC. The OAC and Pediatric Transplantation Committee were opposed to the proposal.

   Public comments received for the OneLegacy proposal were 77% in support, with 23% opposed. All 11 Regions supported the proposal as written. The following committees were in support of the proposal Operations, OPO, PAC, and TCC. The OAC and Pediatric Transplantation Committee were opposed. The Ethics Committee stated some concerns with the proposal, but no vote was taken.

   Several concerns were expressed about the level of consent provided to the index patient; these concerns were addressed by Region 2 and OneLegacy in their responses. The Region 2 response stated that the consent process for transplant candidates is established by individual transplant centers and is not part of OPTN/UNOS policy. OneLegacy stated that "centers conform with CMS requirements to follow and document their established practices for fully informed consent, which includes accepting a split liver." Current OPTN/UNOS policy does not specify any requirements for consent for split liver transplants.

   Several comments expressed the concern that the match run would not be followed under these proposals. Both Region 2 and OneLegacy reiterated that offers will be made in the order of the standard match run, and that the turndown reasons will be reported to UNOS when documenting the placement of the left lateral segment into the most suitable candidate.

Both proposals stated that an automatic hold would be placed on the procedure if the retransplant rate "exceeds 5 of the 20 grafts." Regional and individual commenters felt that this threshold is too high. OneLegacy agreed to reduce the threshold for stopping the study from five re-transplants to three; however, Region 2 did not agree to this, stating that "there may be a learning curve associated with splitting at some centers, 25% retransplant rate was considered reasonable by all centers in the Region." This appears to be the only difference between the two proposals after modification post public comment. Current OPTN/UNOS Policy does not include any threshold for retransplants related to split liver transplantation.

Committee members were in favor of forwarding these two AASs to the Board, assuming that (1) the adult index patient receives appropriate informed consent; (2) the appropriate pediatric patient is chosen and refusal reasons are provided for any potential recipient above the actual recipient; (3) assessment after either 10 splits or two years; and (4) if there are significant retransplants, the AAS will be placed on hold. It was also understood that the index patient would have the option to refuse a split liver and keep the whole liver. The Committee may consider proposing a Committee–sponsored AAS that would allow other areas of the country to opt in to such an agreement. These proposals do not require programming. The Committee submits the following resolutions for consideration by the Board of Directors:

**** RESOLVED, that the proposed Region 2 Split Liver AAS, as set forth in Exhibit C, shall be approved, effective November 9, 2010, and pending notification to the participants.**

Committee Vote: 17 in favor, 0 opposed, 0 abstentions

**** RESOLVED, that the proposed OneLegacy Split Liver AAS, as set forth in Exhibit E, shall be approved, effective November 9, 2010, and pending notification to the participants.**

Committee Vote: 17 in favor, 0 opposed, 0 abstentions

3. Region 8 AAS ("Share 29"). The Region 8 "Share 29" AAS was implemented in May 2007, and the initial application specified an ending date of May 9, 2009 (two years). The Region later voted to extend this to November 8, 2009, to allow further analysis. Since the AAS has expired, and the OPTN Final Rule specifies that variances must be time-limited, the Committee should make a recommendation to the Board regarding its continuance. Data from the AAS has been reviewed during several committee meetings, during the Forum in April 2010, and at the American Transplant Congress in June 2010. The Committee has been considering the Region 8 AAS as a potential model for tiered-sharing that could be proposed for consideration as a national policy.

   During the May 2010 Region 8 meeting, participants voted to dissolve the AAS. An official ballot was distributed, and 11 of the 16 participants favored dissolving the AAS, with 4 opposed and 1 abstention. Many of the comments from those wishing to dissolve the AAS indicated that the AAS did not provide any benefit to patients, while increasing costs to centers. Committee members questioned whether the limited impact of the AAS was related to the small number of patients and transplants involved. Other members noted that patients waiting for a combined liver-kidney

transplant are not eligible for a kidney offer under the AAS, but were included in the analyses. The Committee asked for the analysis to be updated to exclude the liver-kidney candidates. The Committee also asked for the number of times a liver was offered to a candidate with a MELD/PELD score of 29 or higher as a result of the AAS, but was turned down by that candidate and transplanted into a candidate with a lower MELD/PELD score. The Committee agreed to review these data during the October 2010 meeting.

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

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

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

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

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

The Committee has been considering tiered sharing, such as the Region 8 AAS, as a possible model for a national proposal. The U.S. House of Representatives' conference report that accompanied the 2010 Appropriations Bill states that, "Further, the conferees direct that any policy change on broader allocation of livers be tested first in demonstrations, similar to the demonstration recently conducted in Iowa and North and South Dakota, before nationwide implementation, and be made in an incremental manner, reflecting the accumulation and analysis of data on the impact of policy changes." Committee members felt that it is important to fully understand the potential impacts of such a system while there is a regional demonstration project currently in place. Additional data could include a power analysis, the share type (local, regional) and OPO type (single versus multiple center) for those recipients who received transplants with MELD/PELD scores less than 29. Committee members felt that extending the AAS for some specific period of time that would allow these additional analyses to be reviewed was important[1]. Members also recognized that 69% of participants voted to discontinue the AAS, and expressed caution about enforcing an AAS on a region that has voted to discontinue it. Dissolution of the AAS will require programming in UNet^{SM}, and there is no timeline currently available for when that programming would fall in the schedule of work.

A motion to table a vote on the AAS was made, seconded, but then withdrawn. In light of the options provided in Policy 3.4.8.1, the Committee submits the following resolution for consideration by the Board of Directors:

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

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

The Resource and Impact Statement for *removing* the AAS is included as **New Exhibit L**.

II. Other Significant Items

4. Updates on the Ongoing Policy Development Process. During the May 26, 2010, conference call the Committee reviewed its activities over the past year, leading up to the Forum on Liver Allocation and Distribution held in April 2010 in Atlanta, GA. As part of the deliberative process that must be followed before any proposal is circulated for public comment, the Committee's identified the goal(s) of any potential policy change. The Board approved a set of goals and metrics developed by the Committee in 2005, which were based on several of the principles of the OPTN Final Rule. These goals and metrics were included in the RFI that was circulated in December 2009 in preparation for the Forum. During the May 2010 call, the Committee reviewed a proposed draft goal statement that is a more concise version of the Board-approved goals.

   After several wording changes, the Committee approved the following policy goal:

[1] The initial Committee vote was for the AAS to be extended for six months; subsequent to the Committee vote, a decision was made to extend the time to June 30, 2011, following the next Board meeting in June 2011. This will allow the decision regarding programming to be made at an appropriate time with regard to the schedule of work.

To reduce waiting list mortality, without reducing post-transplant survival, by:

- Increasing patient access for transplantation by reducing geographic disparities to the extent feasible;
- Facilitating timely and appropriate placement of organs; and
- Maximizing utilization of donor organs.

The Committee discussed the possibility of circulating a concept paper in the fall of 2010. This would include several of the concepts that seemed to be acceptable to the community based on the feedback from Forum. Much of the feedback indicated that changes to distribution should happen in small, incremental steps. Two such steps could include "Share 35 Regional"(or 32, 29, etc.) and "Share 15 National," possibly combined with the "risk-equivalent threshold" (RET). These could be proposed as individual concepts or in combination. The RET has not been modeled yet; however, the concept may be important in helping the community feel more comfortable with broader sharing, knowing that a liver would not be shared regionally if there is an similarly sick patient locally. It may also mitigate concerns about the differences in the INR value between laboratories. These concepts could also be proposed as regional alternative allocation systems (AAS). The concept paper would be used to foster further discussion and prepare/inform the community before anything is submitted for public comment.

During the July 13, 2010, conference call, the Committee reviewed its work over the last year in somewhat more detail, for the benefit of new Committee members. As noted during the May call, the Committee spent much of 2009 and early 2010 preparing for the Forum. This included circulating an RFI and survey in December 2009. The feedback from the RFI was used to structure the Forum content. The Committee reviewed over 20 different potential changes to the allocation and distribution of livers, many of which were modeled using the Scientific Registry for Transplant Recipient's (SRTR) Liver Simulation Allocation Model (LSAM). These included:

- Local Tiered Share (MELD 15 or 17 / MELD 22,25, 29, 35)
- Regional Tiered Share (MELD 15 or 17 / 22, 25, 29, 35)
- Share 15 National
- Concentric circles (500mi) (22,25, 29, 35)
- Concentric circles (250mi) (22,25, 29, 35)
- Thoracic Zones (standard, with 29 Share, 5 Zones)
- Share Positive Benefit
- Regional Sharing using Transplant Benefit
- MELD-NA / MELD-NA Regional

Feedback from the Forum indicated that most individuals feel that the MELD score is still appropriate for allocation. Any change to the distribution of livers should be made in incremental steps. Strong feelings were expressed about geographic inequities. There was much discussion about OPO effectiveness and the impact of single-center OPOs. There appeared to be moderate to significant support for some level of "tiered sharing," including extending the Share 15 nationally, as well as the concept of a "risk-equivalent threshold." The use of concentric circles, as is used for thoracic organ allocation, did not seem to have as much support. Forum participants discussed the need for mechanisms to increase utilization/decreased discards, and for expedited placement of livers. The

Committee members recognized the need to work more closely with the OPO community on these issues.

Following the Forum, a new subcommittee on Liver Utilization was created to investigate a process for expedited placement, as well as ways to increased utilization and reduce discards of livers. The Committee also sought further direction from Board of Directors. During the June 2010 Board of Directors meeting, the Board approved the following resolution:

*** *RESOLVED, that the Liver and Intestinal Organ Transplantation Committee shall be charged with making recommendations to reduce geographic disparities in waitlist mortality.*

The Committee further discussed a concept paper that would summarize the concepts that seemed to have support based on the Forum feedback (Share 35 Regional (or 32, 29, etc.), Share 15 National, the RET, and expedited placement). This would allow feedback prior to any proposal being submitted for public comment. During the September 2010 conference call, members were informed that two committee members had begun to write the concept paper, which should be ready for Committee review in October. It would then be sent to the Executive Committee for its review and possibly circulated to the public in late 2010.

5. Health Resources and Services Administration (HRSA) Interpretation of FY 2010 Appropriations Bill Conference Report Language. During the July 13, 2010 conference call, the Committee discussed a letter that had been sent to UNOS from the Director of the Division of Transplantation, HRSA, HHS, regarding the language included in the House Conference Report that accompanied the 2010 Appropriations Bill (**Exhibit G**). The letter stated that the report included three requirements that must be met before any policy that would broaden the distribution of liver could be implemented:

    - Six months prior to it being implemented, a detailed report must be submitted to Congress describing the potential impacts of such a change;
    - The House and Senate Appropriations Committees must be notified of such a change; and
    - Prior to nationwide implementation, any such change is to be tested in demonstrations and made in an incremental manner.

    These requirements would not apply to changes liver allocation, i.e., changes to the MELD/PELD score or use of transplant benefit. The letter noted that the third requirement could be conducted using variances, which is the mechanism outlined in the Final Rule to assist the OPTN in determining whether a proposed policy should become national policy. Therefore, if one of the current variances (e.g., Region 8) were to be proposed for national policy, these could be counted as meeting the third requirement. Simulations such as LSAM runs would not meet the requirement.

    A member asked about the proposal to broaden distribution of adult donors to liver-intestine candidates, which includes a national distribution unit similar to the pediatric donor algorithm. It could be argued that an experiment has been conducted, but with a different age group. Similarly, an argument could be made that a "Share 15 national" has been demonstrated on a regional basis, as "Share 15" has been tried in all 11 Regions since 2005. The Region 9 sharing agreement could possibly be seen as an experiment in full regional sharing. The Region 8 "Share 29" AAS could

perhaps be used to support regional sharing at some higher threshold, such as 35 or 32. Committee members raised several other questions:

- Who will decide if a demonstration project and the report to Congress are satisfactory?
- Would it make sense to program a new policy if it could later be determined to be unsatisfactory?
- Is there a way to determine ahead of time what might be satisfactory?
- Will the requirements remain in effect beyond 2010, as this is tied to the 2010 appropriations?

It is not clear what its applicability the 2010 language will have if it is not included in the 2011 Appropriations Bill. The Committee will continue to evaluate improvements to allocation and new approaches to improve liver distribution.

6. Analysis of "Low MELD" Candidates/Recipients**.** The issue of transplanting of 'low MELD' patients was brought up several times during the Forum in April 2010, and in the Committee's subsequent discussions. The Committee has been discussing the "Share 15 National" concept, which would offer livers locally, regionally, and nationally to candidates with a MELD/PELD score of 15 or higher before any candidate with a MELD/PELD score of less than 15. In order to assess the potential impact of this, the Committee was interested in understanding the characteristics of candidates who are on the list or are transplanted with a MELD/PELD score of less than 15. One group of patients that could be disadvantaged are those with low calculated MELD scores and low serum sodium (hyponatremia), who are at higher risk of mortality than their calculated MELD score would indicate. During the July conference call a subcommittee was appointed to review potential enhancements to the MELD score, including the addition of serum sodium.

   During the September 7, 2010 conference call, the following data were provided (**Exhibit H**):

   - Characteristics of patients receiving a deceased donor transplant between January 1, 2007 and December 31, 2009;
   - Characteristics of candidates waiting as of January 31, 2009; and
   - Waiting list death rates.

   Three groups of candidates and recipients were compared: those with a calculated MELD/PELD of less than 15 ("low M/P"); those with a score of 15-24 ("medium M/P"); and those with a score of 25 or higher ("high M/P"). In summary, for patients waiting for a liver:

   - Among regions, 59%-77% were low M/P;
   - Among single center DSAs, 25%-78% were low M/P; and
   - Among multiple center DSAs, 34%-93% were low M/P

   These data were also provided by blood type, ethnicity, gender, age, serum sodium level, and those with a MELD/PELD exception.

   For transplanted patients:

   - Among regions, 2%-8% were low M/P;

- Among single center DSAs, 0%-20% were low M/P ; and
- Among multiple center DSAs, 0%-10% were low M/P

These data were also provided by recipient factors (blood type, ethnicity, gender, age, serum sodium level, and those with a MELD/PELD exception) and donor factors (ethnicity, gender, age, donor risk index, and cold ischemia time). Those patients transplanted with a low M/P score were transplanted with donors that had a higher average DRI ($p<0.001$).

For patients waiting, those with high M/P scores (exceptions excluded) had death rates that were four times that that of low M/P candidates. Among the candidates who died, high M/P candidates were nearly twice as likely to die within one year from multiple organ system failure or infection than when compared to low M/P candidates. High M/P candidates were more than 11 times more likely to be transplanted within one year as low M/P candidates. Following transplant, outcomes for low M/P recipients were nearly identical to those for medium M/P (15-24) recipients for the first year, while high M/P recipients had the lowest survival rates. Committee members commented that many transplants in low-MELD patients may be the result of directed donations, or may be pediatric patients.

Subcommittee/Working Group Updates

7. Intestine Working Group Update. The Working Group proposed a change to the adult donor allocation sequence for Liver-Intestine candidates, which was supported by the Committee in April 2010. This would provide access to the national donor pool for these candidates if there are no local candidates with a MELD/PELD score of 29 or higher, similar to the pediatric donor algorithm. These candidates have twice the mortality rate than candidates waiting for a liver alone.

   During the July 2010 conference call, Committee members expressed concerns that the mortality data should not be strictly compared to liver-alone candidates in aggregate, because these candidates compete for donors with small adult females. Committee members felt that this criticism is likely to be raised, and should be addressed before public comment. Also, the choice of a MELD score of 29 was somewhat arbitrary, which could be criticized. Committee members discussed the recommendation to restrict the policy to candidates with short-bowel syndrome. While there may be other candidates that would be suitable for inclusion, these would have to meet strict criteria. This could be handled by some type of committee or regional review, similar to the process for Status 1A/B cases not meeting criteria. The Committee felt that this proposal should be submitted for public comment in the spring of 2011, rather than in the fall of 2010, allowing time to enhance the proposal and include all the necessary data.

   During the September 2010 conference call, the Committee reviewed waiting list death rates for liver-alone and liver-intestine candidates based on their height, as a proxy for small size/stature (**Exhibit I**). An analysis of all adult candidates listed for liver-alone and liver-intestine at any point during 2008-2009 showed that adult liver-intestine candidates were 2.8 times as likely to die on the waiting list as were adult liver-alone candidates. Among adult liver-alone candidates, those whose height was 5’2” or under were 1.12 times as likely to die on the waiting list than were taller candidates (**Figure 1**). Among adult liver-intestine candidates, those whose height was 5’2” or under were 1.12 times as

likely to die on the waiting list than were taller candidates, but the increased risk was not statistically significant (**Figure 2**).

Figure 1

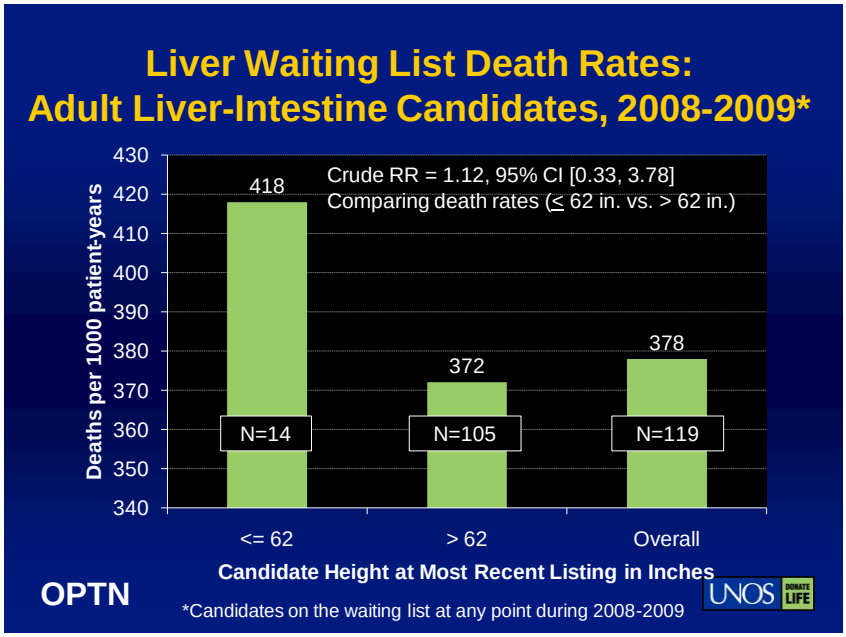
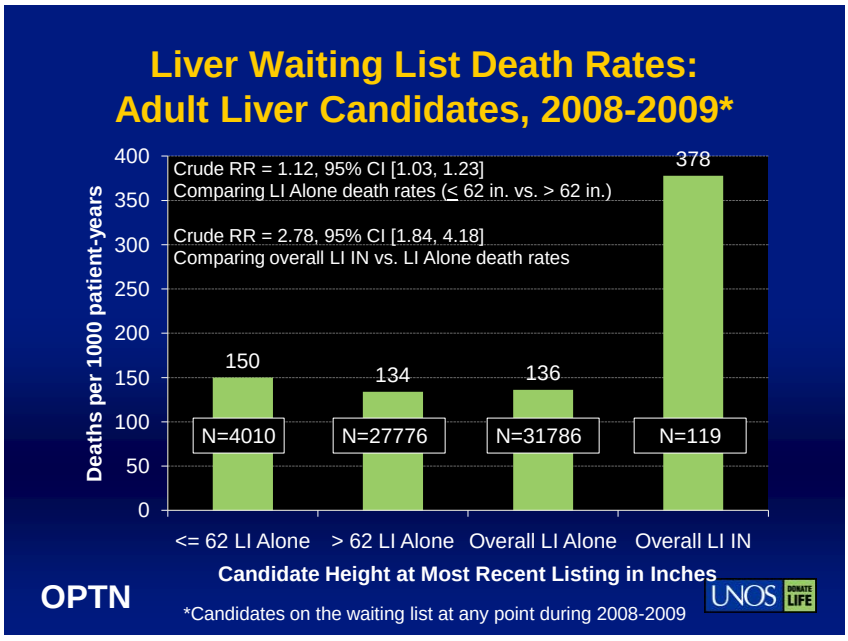


Figure 2



Committee members noted the low number of candidates whose height was less than 5'2", and asked that the time period of the cohort be expanded to capture more patients of small stature. There were still concerns about the impact on small adults, especially small females. However, these candidates may be eligible for a split liver transplant, whereas liver-intestine candidates must receive both organs. The Committee also asked that the updated analysis provide the proportion of males versus females. Finally, the Committee asked to review an analysis produced by the SRTR in 2009 that

compared waiting list mortality rates for liver-intestine and liver alone candidates at each MELD score.

8. Hepatocellular Carcinoma (HCC) Subcommittee Update. The Subcommittee has been developing recommendations for policy changes based on the HCC Consensus conference held in November 2008. These recommendations included the following topics:

    - Post-transplant pathology form;
    - Imaging criteria;
    - Expanding beyond Milan criteria;
    - Guidelines for ablative therapies;
    - Downstaging; and
    - An HCC allocation Score.

    The conference recommendations for imaging criteria have been incorporated into draft policy language. While the policy will still only include tumors within the Milan criteria, tumors would be grouped into different classifications (OPTN Class 0 – 5), and only Class 5A or 5D lesions would be eligible for automatic upgrade. The imaging would have to be performed at the transplant center, or reviewed by a multidisciplinary conference at the center. Committee members were concerned that the criteria are too complicated and detailed to be implemented on a national level. Further, there may be opposition due to fears of increased costs either for equipment or for re-reading of scans. The Subcommittee is proposing to survey transplant programs to determine their initial response prior to circulating a proposal for public comment (**Exhibit J**). The survey should include a flow chart illustrating the policy. Committee members noted that this is not dictating practice, but determining who is eligible for exception points, and that the current policy already includes some requirements for imaging.

    The Committee discussed the recommendation for an allocation scoring system for candidates with HCC. Patients with HCC exceptions may still be receiving too much priority on the waiting list. Recent analyses have shown that candidates without HCC drop off the waiting list for death or becoming too sick at a higher rate than those with HCC exceptions.

    The recommendation was for a continuous score (rather than a fixed number of points, as is done currently) that would incorporate the candidate's calculated MELD score, AFP, tumor size and rate of tumor growth. The score would only apply to candidates with T2 lesions, but all candidates with HCC would be designated as such on the waiting list. Other components of the conference report recommendation included:

    - The candidate must be within Milan criteria (MC) for a minimum of 3 months (based on date of first imaging study documenting a lesion within MC) before additional points are assigned.
    - Patients with a diagnosis of HCC within MC and a calculated MELD score < 15 will start with a MELD/HCC priority score of 15 until they have had the HCC diagnosis for 3 months, then they will receive the calculated MELD/HCC priority score.
    - Patients with a calculated MELD score > 15 will receive their calculated MELD until the 3 months since the diagnosis of HCC within MC have elapsed, then they will receive their calculated MELD/HCC priority score. MELD/HCC priority score will be recalculated every 3 months and can increase or decrease according to changes in tumor characteristics,

underlying MELD score and time within MC. Patients with elevated AFP and no tumor by imaging will no longer receive additional MELD points.

Committee members felt that the concept is appealing, but very complicated. Further, any policy proposal will need to be supported with data. One important source of data will be the post-transplant pathology report, but these data are not currently available, and will not be available until an on-line form is implemented. Committee members felt that this proposal should be tabled until more reliable data are available, and that perhaps several large centers could pool their data as a starting point.

9. Status 1A/B Review Subcommittee. Starting in August 2010, the reviews of Status 1A/1B listings that do not meet criteria will be conducted on a more real-time basis, similar to what is being done for the MELD/PELD exception cases. This new process will provide better and timelier feedback to the members.

10. MELD Exceptions Subcommittee. The Committee reviewed the trend in MELD/PELD exception applications between 2005 and 2009. The number of exception requests has been increasing, especially for "Other specify" diagnoses and "HCC not meeting criteria." The number of new registrations on the list was stable over that same time frame. Committee members felt this reflected the increase in MELD/PELD scores required to receive an organ offer. The publication of guidelines for exceptional case diagnoses in the MELD Exceptions Study Group (MESSAGE) conference paper may have also contributed to an increase in applications. The Committee took no further action.

    Policy 3.6.4.5.2 (Liver Candidates with Cholangiocarcinoma) requires that centers who wish to submit exception applications for candidates with CCA to submit their CCA protocols to the Committee. The Exceptions Subcommittee has reviewed 14 CCA protocols to date. Six were approved by the full Committee in February 2010. Of the remaining eight protocols, the subcommittee recommended that four should be approved as is, and three to be approved with some comment back to the center. One protocol could not be approved, as it included intra-hepatic CCA, which falls outside the criteria outlined in the policy. In that case, the subcommittee recommended that the center create two separate protocols: one with full RRB submission for intrahepatic lesions, and one that meets the stated policy criteria for hilar CCA, which could be submitted for standardized exception to the RRB chair. In two cases, the Subcommittee was concerned about the center's plan to stage the CCA at time of organ availability, but felt that if there is agreement within the OPO regarding use of a backup, and the center has access to on-call pathologists for staging, then the protocol would be acceptable. In one other case, the subcommittee was concerned that the center indicated that it would perform a transperitoneal biopsy if the center could obtain tissue endoscopically. The policy states that "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," but does not require that this practice must be avoided. The Committee supported the subcommittee's recommendations by a vote of 14 in favor, 0 opposed, and 0 abstentions.

Other Items

11. Update on the UNet^{SM} Forms Proposal. The proposal to revise the data submission forms circulated for comment in March 2010 was put on hold due to concerns expressed by the professional societies. A call was held on May 24, 2010 with representatives from the ASTS, AST, SRTR, HRSA, and

UNOS. During that call, it was decided that data elements related to the program-specific reports (PSRs) will not be going to the Board at this time. These constitute the vast majority of new data elements proposed. A reduced list of data elements will be submitted to the AST and ASTS for their comments, followed by submission to the Policy Oversight Committee. The proposed post-transplant pathology form will be included on the reduced list. Committee members reiterated their desire that the form move forward.

During the July 2010 conference call, Committee members were asked if they would object to the deletion of panel reactive antibody (PRA) from the Recipient Histocompatibility form for liver recipients. Several Committee members felt that these data elements should remain on the form, as recent analyses showing that donor-specific antibody (DSA) is related to chronic rejection. However, in a subsequent poll of the Committee, most indicated that these data would be useful for research purposes only, and should not be included on OPTN data collection forms.

12. Memorandum from the Department of Evaluation and Quality (DEQ) Concerning MELD/PELD "Rollbacks." Policy 3.6.4.1.1 requires that MELD/PELD score reassessment and recertification "must be based on the most recent clinical information (e.g., laboratory test results and diagnosis), including the dates of the laboratory tests." Members may perform more recent lab tests, but opt not to enter them until they are required based on the recertification schedule, which is acceptable. However, there have been cases when a center enters new lab values prior to the required recertification date, and these new values lower the MELD/PELD score. The center then asks UNOS to "roll back" (rescind) the more recent values. Committee members felt that this is not permissible. However, one member noted that when their center was audited, the center was "written up" for cases when the MELD/PELD score had not expired, but more recent labs were available. The Committee asked for clarification from DEQ regarding this issue.

13. SRTR Program Specific Reports (PSRs). During the September call, Committee members discussed the reporting mechanism used by the SRTR PSRs. The MELD/PELD score that is reported at the time of transplant is the calculated/laboratory score and not the score used by the match at transplant, which would include those with exception scores. Although there is a footnote that explains this, it is being misinterpreted by insurance companies. The table is intended to provide patient characteristics (i.e., the calculated MELD/PELD score) and not characteristics of the allocation system (i.e., the match score). The SRTR has developed an alternative mechanism for reporting MELD/PELD at transplant; a link to an SRTR report with this methodology will be provided to the Committee.

Committee Participation
May 26, 2010 Conference Call

NAME	COMMITTEE POSITION	In Attendance
W. Kenneth Washburn, M.D.	Chair	X
Kim Olthoff, M.D.	Vice Chair	X
Michael Curry, M.D.	Regional Rep.	X
Stephen Dunn, M.D.	Regional Rep.	
Nigel Girgrah, M.D., Ph.D.	Regional Rep.	X
Goran Klintmalm, M.D., Ph.D.	Regional Rep.	X
Ryutaro Hirose, MD	Regional Rep.	X
John Ham, M.D.	Regional Rep.	
Anthony D'Alessandro, M.D.	Regional Rep.	X
Harvey Solomon, M.D.	Regional Rep.	
Thomas Schiano M.D.	Regional Rep.	X
Shawn Pelletier, M.D.	Regional Rep.	
James Eason, M.D.	Regional Rep.	
Maureen Burke-Davis, RN, NP-C,	At Large	
Patricia Carroll PA-C, CPTC	At Large	X
Julie Heimbach, M.D.	At Large	X
Heung Bae Kim, M.D.	At Large	X
Timothy McCashland, M.D.	At Large	
Lisa McMurdo, RN, MPH	At Large	X
Scott Biggins, M.D.	At-Large	X
Kenyon Murphy	At Large	X
John Roberts, M.D.	At Large	X
Debra Sudan, M.D.	At Large	X
Kerri Wahl, M.D.	At Large	
Elizabeth Pomfret, M.D., Ph.D.	Ex Officio	
Christopher McLaughlin	Ex Officio - HRSA	X
James Bowman, MD	Ex Officio – HRSA	X
Robert Walsh	Ex Officio – HRSA	X
Bernard Kozlovsky, M.D., MS	Ex Officio – HRSA	X
Monica Lin, Ph.D.	Ex Officio – HRSA	X
Ba Lin, PhD	Ex Officio – HRSA	X
Mary Guidinger, MS	SRTR Representative	X
Ann Harper	Committee Liaison	X
Erick Edwards, Ph.D.	Asst. Dir., UNOS Research	X
Jory Parker	UNOS Business Analyst	X
Aaron McKoy	UNOS Dept. Evaluation & Quality	X
Leonard Carinci	UNOS Dept. Evaluation & Quality	X

Committee Participation
July 13, 2010 Conference Call

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	
Jorge D. Reyes, MD	Regional Rep. Region 6	X
Anthony D'Alessandro MD	Regional Rep. Region 7	X
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	X
Timothy McCashland MD	At Large	X
Kenyon Murphy	At Large	X
John Roberts MD	At Large	X
Debra Sudan MD	At Large	X
Kim Brown, MD	At Large	X
Kareen Abu-Elmagd, MD	At Large	X
Michael Charleton, MD	At Large	X
James Trotter, MD	At Large	X
James Eason, MD	At Large	X
Christopher McLaughlin	Ex Officio - HRSA	X
Bernard Kozlovsky, MD	Ex Officio - HRSA	X
Nate Goodrich	SRTR Representative	X
Robert Merion	SRTR Representative	X
Diane Steffick	SRTR Representative	X
Mary Guidinger, MS	SRTR Representative	X
Brian Shepard	UNOS, Dir. of Policy	X
Erick Edwards, PhD	Asst. Dir., UNOS Research	X
Ann Harper	Committee Liaison	X

Committee Participation
September 7, 2010 Conference Call

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	
Jorge D. Reyes, MD	Regional Rep. Region 6	X
Anthony D'Alessandro MD	Regional Rep. Region 7	X
Harvey Solomon MD	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
Scott Biggins MD	At Large	X
Julie Heimbach MD	At Large	X
Heung Bae Kim MD	At Large	X
Timothy McCashland MD	At Large	
Kenyon Murphy	At Large	X
John Roberts MD	At Large	X
Debra Sudan MD	At Large	X
Kim Brown, MD	At Large	
Kareen Abu-Elmagd, MD	At Large	X
Michael Charlton, MD	At Large	X
James Trotter, MD	At Large	X
James Eason, MD	At Large	X
Tom Mone	At Large	X
Monica Lin, PhD	Ex Officio - HRSA	X
Bernard Kozlovsky, MD	Ex Officio - HRSA	X
James Bowman, MD	Ex Officio - HRSA	X
Nate Goodrich	SRTR Representative	X
Robert Merion	SRTR Representative	X
John Magee, MD	SRTR Representative	X
Steve Colquhoun, MD	OneLegacy	X
Miryam Mehta	OneLegacy	X
Brian Shepard	UNOS, Dir. of Policy	X
Chrystal Graybill	UNOS, Regional Administrator	X
Erick Edwards, PhD	Asst. Dir., UNOS Research	X
Ann Harper	Committee Liaison	X
Jory Parker	UNOS Business Analyst	X

Committee Participation
October 20, 2010 Meeting

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	
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	X
Lewis Teperman, MD	Regional Rep. Region 9	X
John Fung, MD, PhD	Regional Rep. Region 10	
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	X
Timothy McCashland MD	At Large	X
Kenyon Murphy	At Large	X
John Roberts MD	At Large	X
Debra Sudan MD	At Large	X
Kim Brown, MD	At Large	X
Kareen Abu-Elmagd, MD	At Large	
Michael Charlton, MD	At Large	X
James Trotter, MD	At Large	X
James Eason, MD	At Large	X
Tom Mone	At Large	X
Chris McLaughlin	Ex Officio - HRSA	X
James Bowman, MD	Ex Officio - HRSA	X
Nate Goodrich	SRTR Representative	X
Robert Merion	SRTR Representative	X
Ray Kim, MD	SRTR Representative	X
Dave Zaun	SRTR Representative	X
Charles Alexander	OPTN/UNOS President	X
Maureen McBride, MD	UNOS, Dir. of Reseqarch	X
Brian Shepard	UNOS, Dir. of Policy	X
Ciara Samana, MSPH	UNOS, Asst. Dir. of Policy	X
Erick Edwards, PhD	Asst. Dir., UNOS Research	X
Ann Harper	Committee Liaison	X
Michael Voigt. MD	Guest, Univ. Of Iowa	X