# Liver and Intestinal Organ Transplantation Committee
**November 14, 2012**
**Conference Call**
**INTERIM REPORT**

1. Brief Board Meeting Update. The "HCC Hold" proposal was not approved by the Board of Directors at the November 12-13, 2012 meeting, due to concerns about its cost relative to the benefit it might provide.

2. Geographic Redistricting for Distribution of Livers. On November 12, 2012, the OPTN/UNOS Board of Directors approved the following resolution from the Policy Oversight Committee (POC):

   RESOLVED, that the Board of Directors approve the following position regarding geography in organ allocation:
   - The existing geographic disparity in allocation of organs for transplant is unacceptably high.
   - The Board directs the organ-specific committees to define the measurement of fairness and any constraints for each organ system by June 30, 2013. The measurement of fairness may vary by organ type but must consider fairness based upon criteria that best represents patient outcome.
   - The Board requests that optimized systems utilizing overlapping versus non-overlapping geographic boundaries be compared, including using or disregarding current DSA and region boundaries in allocation.

   Dorry Segev, MD, and Sommer Gentry, PhD, presented an update on their redistricting project to the Committee. They have been working on this concept for liver distribution over the last four years, first under an NIH Challenge Grant, and now under the SRTR contract. Regarding the measurement of fairness, there is a distinction between summative metrics, which are what the community is accustomed to using, and disparity metrics. Summative metrics consider one national outcome, such as total waitlist deaths, total deaths pre and post transplant, or the fraction of organs transplanted for MELD scores below 15. Another example of a summative metric is net transplant benefit, which was proposed for kidney allocation. Disparity metrics directly measure differences across geographic units, such as the variance of the median MELD score at transplant, death or transplant rates, or distances, across and between DSAs. For example, the rate of death or transplant for a given MELD score varies greatly across DSAs. These are the types of fairness metrics that the Board resolution addresses. It is possible to improve summative metrics while worsening disparities metrics. For example, broader sharing using the current regions may actually increase the variance in the median MELD score at transplant (although using optimized regions can decrease this variance).

   The work is being conducted in phases, with phase 1 using the current DSAs to create optimal organ sharing districts. The underlying mathematics for this has been developed and is ready for Committee's input. Phase 2 would be based on something other than the current DSAs, such as concentric circles (either based on distance or transport time or population), with districts that overlap (nicknamed overlapping "amoebas") or dynamic overlapping "amoebas" where the priority for organ offers could be determined in real time, in response to "inequity-to-date," using a score that balances the MELD score against transport time, for example. The mathematics for those analyses is several years away.

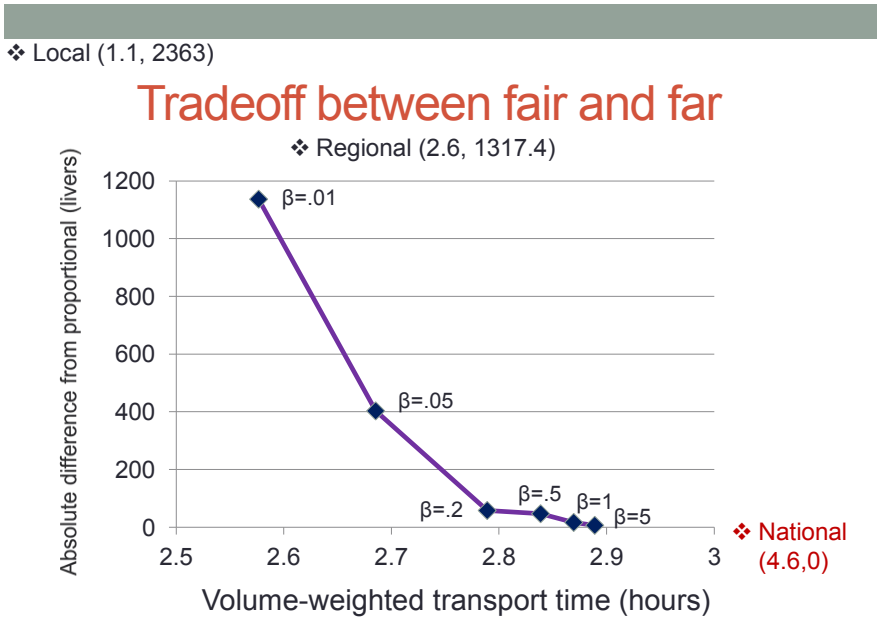
In order for the SRTR team to complete phase 1 and design the most optimal redistricting system, the Committee must select a primary disparity metric and determine the appropriate tradeoffs between geographic fairness and transport time. The Committee must also choose the number of districts preferred and determine whether districts must be contiguous, and identify additional metrics to track when the SRTR is testing the optimized maps.

Possible disparity metrics include:

- The variance of median MELD at transplant across geographic units
- The sum of absolute differences from proportional allocation of livers
- The variance of per-day waitlist death rate for candidates across geographic units
- The variance of per-day transplant rate for candidates across geographic units

There are plusses and minuses associated with each metric. “Proportional allocation” is the proportion of organs each geographic unit would receive if every organ went to highest MELD candidate anywhere in the country, measured by how similar the proportions are. The farther away (numerically) a system is from proportional allocation, the less “fair” the system is considered to be. The algorithm next calculates the volume-weighted organ travel time between DSAs in each district (“far”), with the ‘goal’ being to find best tradeoff between “fair” and “far.” Figure 1 shows the trade-offs between the two using various distribution systems. The variable beta (β) represents the level of ‘fairness.’ Using only fairness could result in maps that have discontiguous districts, but continuous regions can be a constraint in the model.

**Figure 1**




The mathematical algorithm creates the maps, and then LSAM generates projections using those maps. Various LSAM outputs can be generated to evaluate the maps. The Committee discussed the possible addition of the median MELD score at the time a candidate gets his first offer, as a measure of fairness in access. The Committee was asked to provide feedback via e-mail on the metrics and outcomes, and a survey can be constructed and circulated if needed.

3. MELD Subcommittee Update. The MELD subcommittee has been working on several different projects during its recent conference calls. The Subcommittee has reviewed several drafts of the proposal to add serum sodium to the MELD score. The Subcommittee is recommending that serum sodium values used to calculate the new score should be collected at the same time intervals that are required for the other laboratory values used to collect the MELD currently. The addition of sodium should benefit primarily those individuals with lower MELD scores who have low sodium. This should reduce the number of exception requests for candidates with ascites. This proposal will be circulated for public comment in the spring of 2013.

   The Subcommittee has also been reviewing data related to recipients of DCD livers who subsequently develop biliary strictures and require retransplant, for development of a possible standardized MELD exception for these candidates. These recipients reportedly have a higher risk of relist and retransplantation, although their risk of death without a transplant is not necessarily higher. The quality of life is likely poorer, but the MELD allocation system was not designed to address quality of life. Outcomes for recipients of DCDs seem to be improving over time as more experience is gained in terms of appropriate selection of recipients and organs. The Subcommittee has been discussing additional criteria that would be required to receive an exception. One alternative is to develop guidelines for RRB approval, as opposed to policy. For example, prior to the standardized exceptions being included in policy, the Committee issued them as guidelines.

   The Subcommittee has also discussed ways to make the MELD exceptions process more transparent and consistency across the county. One way to do this is to provide more data about the exception practices in different regions. The Subcommittee suggested that the percentage of transplant with MELD exceptions be released by center, at a minimum to program directors and regional meetings. Several regions have requested these data for their regional meetings. However, current OPTN data release policies would not allow this unless each center gives its permission. The Policy Oversight Committee (POC) has the authority to determine additional data elements that are releasable by center, and the subcommittee requested that the Committee request that the POC add 'transplants by exception' to the list. The Committee did not act on this request.

   The Subcommittee was asked to develop additional guidelines for approval of MELD exceptions for the RRBs.

4. Intestine Subcommittee Update. The Subcommittee has been finalizing its recommendations for proposed bylaws for Membership and Personnel Requirements for Intestine Transplant Programs. Currently there are no requirements for who can be a primary intestine surgeon or physician. The existing bylaws for other organs were used as the model, and the proposed experience thresholds are based on the ASTS' requirements for accreditation of Intestinal transplant surgery fellowship programs. These will be presented to the Membership and Professional Standards Committee in December 2012 for possible spring 2013 public comment.

5. Liver Utilization Working Group Update. During its November 6, 2012 conference call, the subcommittee discussed a new program in Region 9 for placement of imported livers to all centers within the region. This may be a possible template for other regions or DSAs to use. The Subcommittee chair also reported his findings from discussions with various OPO personnel throughout the country regarding organ acceptance and the use of liver biopsies before procurement, as data presented to the Working Group indicates that biopsy is an important factor in the acceptance (or decline) of shared donor livers. Most OPOs are currently performing the biopsies to assist in donor placement, but most are not using an internet-based

pathology tool. Further, there are no universally accepted criteria for when to biopsy, leaving it up to the OPO or receiving center to make that determination. He reported that most OPOs make the “expedited call” to high-acceptance centers, most believing that this is necessary in order to reduce cold time and ultimately place the liver. The Subcommittee expressed concerns about centers who turn down organs once ‘on-site’ and/or post cross-clamp. One idea put forward is that some donor profile could be used to alert OPOs that expedited placement may be needed before procurement.

The Subcommittee was asked to come up with a specific list of recommendations to make DonorNet more efficient for placement of livers.

6. HCC Working Group Update. The Working Group is awaiting LSAM Modeling results for several potential changes to HCC exception policy. Preliminary results were available from the HCC survey circulated to the community in October. Just over half felt that current level of priority assigned to candidates with HCC exceptions relative to other candidates waiting, while 44% said it is appropriate. Forty-three percent felt that the initial score assigned should be lowered, and a similar percentage indicated that scores for HCC exception extensions should be capped (unless there is tumor progression). When asked whether patients listed with well-treated lesions showing no radiographic evidence of viable tumor should demonstrate growth or other new recurrence before HCC exception points can increase, 42% somewhat agreed or strongly agreed. Just over 70% disagreed with the statement that “There should be a waiting time following listing before a candidate may be eligible for an HCC exception score.“ Thus, there was some agreement that the policy may need to change, but no clear agreement about how that should happen. The Working Group will provide a more detailed update during the next call.

**Attendance, November 14, 2012**

| | | |
|---|---|---|
| Kim Olthoff, MD | Chair | X |
| David C. Mulligan, MD | Vice Chair | X |
| Adel Bozorgzadeh, MD | Regional Rep. Region 1 | X |
| Andrew Cameron, MD | Regional Rep. Region 2 | |
| George Loss, MD | Regional Rep. Region 3 | |
| Mark R. Ghobrial, MD, PhD | Regional Rep. Region 4 | |
| Steven Colquhoun, MD | Regional Rep. Region 5 | X |
| Susan Orloff, 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 |
| Milan Kinkhabwala, MD | Regional Rep. Region 9 | X |
| Atsushi Yoshisda, MD | Regional Rep. Region 10 | X |
| Kenneth Chavin, MD | Regional Rep. Region 11 | X |
| Fredric D. Gordon, MD | At Large | X |
| Burnett (Beau) S. Kelly Jr., MD | At Large | X |
| Leona Kim-Schluger, MD | At Large | X |
| Nancy Knudsen, MD | At Large | |
| Manuel Rodriguez-Davalos, MD | At Large | X |
| Kirti Shetty, MD | At Large | X |
| Mike Wachs, MD | At Large | |
| Simon P. Horslen, MB, ChB | At Large | X |
| Thomas Starr | At Large | |
| Fredric G. Regenstein, MD | At Large | X |
| Srinath Chinnakotla, MD, MCh | At Large | X |
| Ryutaro Hirose, MD | At Large | X |
| Julie K Heimbach, MD | Co-Chair HCC Working Group | X |
| James Bowman, MD | HRSA, *ex officio* | X |
| Ba Lin, PhD | HRSA, *ex officio* | X |
| Monica Lin, PhD | HRSA, *ex officio* | X |
| Dorry Segev, MD | SRTR | X |
| Sommer Gentry, PhD | SRTR | X |
| John R Lake, MD | SRTR | X |
| Ann Harper | UNOS, Committee Liaison | X |
| Erick Edwards, PhD | UNOS Research Support Staff | X |