

**INTERIM REPORT**  
**LIVER AND INTESTINAL ORGAN TRANSPLANTATION COMMITTEE**  
**Conference Call**  
**December 14, 2011, 2PM EDT**

1. Update from November 2011 Board of Directors Meeting. The Committee submitted three proposals for Board consideration in November 2011, and all were approved:
  - Proposal for Improved Imaging Criteria for HCC Exceptions (39 in favor, 0 opposed, 0 abstentions).
  - Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates (28 in favor, 9 opposed, 1 abstention).
  - Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation (33 in favor, 1 opposed, 1 abstention).

The first two policies will require programming in UNet<sup>SM</sup>, which will happen sometime after the Chrysalis project is completed in 2012. The Split Liver CAS does not require programming in UNet<sup>SM</sup>. CAS Applications will be available through the Regional Administrators. Once an application is submitted with the requisite signatures, applicants may begin participating in the CAS.

Two changes to liver policies for pediatric candidates were also approved by the Board. Pediatric patients who meet all Status 1 criteria except for being located in the ICU will be eligible for Status 1. Candidates with non-metastatic hepatoblastomas will no longer be required to spend 30 days with a MELD or PELD score of 30 prior to being eligible for Status 1B. These require programming, but until UNet<sup>SM</sup> can be reprogrammed, an interim manual solution will be employed. The Status 1 Review Subcommittee would no longer review these cases, but the Committee will monitor the number of these cases being submitted.

Committee members expressed interest in providing liver transplant programs with a form or template outlining the changes to the HCC exception policy, so that radiologists at liver transplant programs can start using the imaging criteria prior to implementation of the policy in UNet<sup>SM</sup>. This would help programs to become comfortable with the new requirements prior to implementation. The document could be circulated to the community via the monthly e-newsletter.

2. Review of Policy Proposals. The Committee reviewed seven proposals that had been circulated for Public Comment in September 2011.
  - A. Ad Hoc International Relations and Ethics Committees: Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens), Which Include Changes to the Non-Resident Alien Transplant Audit Trigger Policy and Related Definitions. This is a revision of this policy after 20 years of having the “5% rule,” and is intended to provide transparency and accuracy in data collection. The current policy has caused confusion in the community, and centers often perceive this as putting them in the “immigration business.” The proposal

provides a definition of non-resident aliens, and clarifies the process for audit of non-resident alien transplants. These data are currently being required on the forms; however, there are no definitions. Committee members expressed concerns that transplant centers have no way to verify where patients are from; however, the proposal does not require centers to obtain visas, etc , but only information that is self-reported by the patient.

Much of the discussion centered on the '5% rule.' Currently, if more than 5% of a center's transplants are in the non-resident alien population, the center receives a letter of inquiry. This is not a policy violation, but only triggers an inquiry or 'audit.' This proposal will eliminate the 5% audit trigger policy, allowing for review of all listings and transplants of non-citizens/non-residents.

B. Living Donor Committee Proposals. Two Committee members reviewed the proposals circulated by the Living Donor Committee, and submitted this response, which was endorsed by the Committee members participating on the teleconference. Committee members recognized that these proposals relate to living kidney donors, but wanted to provide the Living Donor Committee early feedback if that committee will be developing similar policies for living liver donors.

(i) Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors. The Committee supports the concepts of full informed consent for all living donors, as the OPTN does not currently have a policy for this. However, the Committee has concerns about the duplication of efforts between the OPTN and CMS. The OPTN should be the entity establishing standards of practice within the system to protect living donors. CMS is proposing to revise parts of the Transplant Center Conditions of Participation, and relies on the OPTN for comprehensive evaluation of center performance. Thus, the OPTN must ensure these policies are not redundant or overly burdensome to transplant centers such that patient care is harmed. The OPTN must also take caution to maintain patient confidentiality (and to prevent violations of HIPAA) when a potential recipient's behavioral issues (e.g., smoking, drug use, etc.) are reported to donors as part of the discussion about the possible effects of such behaviors on post-transplant outcomes. Donor safety is paramount, but the recipient's confidential medical history must also be respected when providing full informed consent, which is much more difficult at times with living donors than with deceased donors.

(ii) Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-Up. This proposal reinforces the need for transplant centers to develop a contract with living donors for future follow-up. Complete follow-up data provide for accurate understanding of post-donation outcomes, which is necessary for eliciting true informed consent. The difficulty lies in mandating that volunteers (who are going through major surgery to help another) undergo lab testing at 6 months, 1 year and 2 years after donation. There is no way to require all living donors to comply with mandatory testing, which places transplant centers

at risk if they are unable to achieve the required expectations. Several centers have reported that, despite considerable effort and additional expense, it is extremely difficult to obtain follow-up information from their living donors, especially when the donors are doing well post-donation. For example, even with a grant from the state, programs in NY State were unable to track down all their living donors. The A2ALL research study, which paid coordinators to track down living donors, had a similar experience. Many living donors are from out of state, and while some out-of-state donors can be reached by telephone, it is difficult to get them back to the center for tests.

For these reasons, the Committee feels the compliance rate of 90% should be modified to include documented efforts to contact all donors, rather than the number of donors that have undergone labs, etc. Given the timeline provided, living donor transplant centers will not start capturing this data until early 2013, with follow-up forms due in 2014. This gives adequate time for centers to change culture (i.e., develop expectations with their living donors that this is in everyone's best interest). Centers will have to bear the increased costs, but this is considered part of the cost of performing living donor transplantation.

- (iii) Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors. This proposal was based on guidelines previously developed by the Joint Society Working Group (JSWG) comprised of members of AST, ASTS, NATCO, OPTN/UNOS and HRSA, as directed by HRSA. The guidelines detailed the clinical parameters to be used to perform safe and effective living medical evaluations of living kidney donors, which could then be standardized throughout the country. Many in the community felt the original guidelines were too prescriptive in directing best medical judgment (i.e., specific lab testing and mandatory exclusions), leading to multiple rewrites of the guidelines.

There are some conditions that are described in the current proposal as "relative contraindications" that could be better described as "conditions that may require further investigation or testing to determine donor suitability." The proposal is not clear as to whether every potential donor must undergo all tests required, or only those who actually donate, as many could potentially be ruled out on much less testing and/or on psychosocial screening. The policy is similarly unclear as to whether site auditors will examine the charts of all those being evaluated as potential donors, or only those who go on to donate. There are some concerns about how CMS will interpret these policies. Although the Liver Committee agrees with standardized medical evaluation for living donors, this proposal must be clarified before it will be ready to implement.

- C. Organ Procurement Organization (OPO) Committee: Proposal to Change the Term "Consent" to "Authorization" Throughout Policy When Used in Reference to Organ Donation. The proposal seemed to be straight-forward; the Committee had no additional comments.

- D. Organ Procurement Organization (OPO) Committee: Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions. The Committee had no comments.
- E. Policy Oversight Committee (POC): Proposal to Clarify and Improve Variance Policies. The Committee supports the rewrite, as it is much easier to understand than the current policy language, but has the following comments:
- Time limitations should be defined, and a category should also exist for a variance to continue permanently (e.g., New York’s statewide share).
  - The “75% approval rule” should be clarified. Language might include: “in order for the variance to go forward, the appropriate committee and the Board must have at least approval of 75% of the applying parties.”
  - Committee members felt that the language in the underlined section is unclear and should be revised: "Members wishing to join an existing open variance must submit an application as dictated by the specific variance. If a Member’s application will require other Members to join the variance, the applicant must solicit support from them. When an open variance is created, it may set conditions for the OPTN contractor to approve certain applications. However, if the application to join an existing open variance does not receive affirmative support from all of the Members required to join by the application, the OPTN contractor may not approve the application and only the sponsoring Committee may approve the application."

3. Optimizing Geographic Boundaries to Reduce Disparity in Liver Allocation. Dorry Segev, MD, provided the Committee with an overview of work being conducted in conjunction with the Scientific Registry of Transplant Recipients (SRTR) contractor. The work originated under an NIH Challenge Grant to explore optimization methods in the context of organ allocation; this was presented at the 2011 ATC by Sommer Gentry, PhD. Subsequently, HRSA asked the SRTR to “scale up” these methods as part of the liver community's efforts to address geographic disparities. The presentation described the concepts of “mathematical redistricting” to design optimal regions and “Principles-Based Optimization.” The SRTR is also conducting statistical modeling of organ transport times to characterize the tradeoffs and determine acceptable limits related to broader sharing. Improvements are being made to the Liver Simulated Allocation Model (LSAM) to calculate disparity metrics as model outputs (as opposed to summative metrics, as described below) and to estimate uncertainty (i.e., to calculate true confidence intervals).

Redistricting is a well-known and very challenging operations research problem, often seen in the context of elections and school districting. These methods are being applied to liver distribution. The first step is to design maps that combine DSAs into new regions using an integer programming optimization model. The next step is to evaluate whether these new maps can reduce geographic disparities in liver transplant using LSAM. The concept of concentric circles as used in thoracic distribution has been suggested for livers; this is not redistricting because they are not static maps, but is being examined as well.

Principle-based optimization is optimal redistricting that can design the best regions to meet an *a priori* specified goal (i.e., the principles/goals/constraints must be determined up front). These may include **summative metrics**, such as total deaths or transplants; **disparity metrics**, such as differences in the median/mean MELD at transplant, death or transplant rates by DSA or Region; and **trade-offs**, such as the increase in transport time and distance traveled required to achieve a reduction in disparities. It is possible that, while improving an individual summative metric, broader distribution could actually worsen disparities rather than improve them. The Final Rule lists both summative and disparity metrics. There are several key questions that must be decided by the liver transplant community prior to these analyses, including:

- What types of regions would be impossible as liver distribution units?
- What is the upper limit of transport time in hours?
- Are contiguous regions necessary?
- How many regions are desired?
- Do disparity metrics matter in designing liver allocation, or only summative utility metrics?

The community must also define the metric(s) to be used to reduce inter-transplant program variance (per the Final Rule), as well as what trade-offs are acceptable between increasing transport time and decreasing disparities. Dr. Segev described their ideas for transport time modeling, as well as enhancements to LSAM that will allow the proposed analyses to proceed. These include generating output to show disparities, developing a probabilistic donor and candidate simulator, and exploring an organ acceptance model using strategic behavior modeling instead of a statistical probability model. The team will rely on Committee input when developing output measures, including those relating to costs.

#### 4. Subcommittee Updates:

- A. MELD Enhancements and Exceptions. The subcommittee met by teleconference on September 28, 2011 to review the SRTR's MELD refit and MELD-Na. The subcommittee will reconvene when final analyses are available in early 2012, and will make a recommendation to the Committee regarding revising the MELD score during the March 2012 meeting.
- B. HCC Subcommittee. The subcommittee met by teleconference on October 13, 2011. The subcommittee is exploring ways to modify the allocation policy for candidates with HCC, as there are concerns that in many regions candidates with HCC receive too much priority relative to other candidates. Two options being explored are a continuous score for HCC priority, similar to MELD, and changes to the timing for when candidates could receive additional priority for HCC.

One idea that has been proposed is to allow centers to place a MELD-HCC exception 'on hold' if the candidate has small tumors that have not grown over time. A program may not be ready to transplant such a patient, but cannot put the exception on hold without the candidate losing the

exception (and having to start all over again). The candidate could remain at the latest approved score, while inactive, until the center is ready to transplant the patient. This is primarily an administrative change, and could be circulated for public comment in the spring of 2012. The Committee members on the call were supportive of this proposal.

- C. Liver Utilization. The subcommittee met by teleconference on October 26, 2011 and are awaiting further analyses. The subcommittee is trying to develop a profile for those liver donors that could have expedited placement, and is also exploring how this might be accomplished.
- 5. Liver Biopsy Form. During the October call, the Committee was supportive of the biopsy form and resources developed by the Organ Availability Committee (OAC). Because the OAC has been dissolved, the Liver Committee has been asked to bring this work before the Board. The latest biopsy form and the web link to the accompanying resources will be circulated to the Committee.

**Committee Participation, December 14, 2011**

Kim Olthoff, MD	Chair	X
David C. Mulligan, MD	Vice Chair	X
Shimul A. Shah, MD	Regional Rep. Region 1	
Andrew Cameron, MD	Regional Rep. Region 2	
Brendan McGuire, MD	Regional Rep. Region 3	
Mark R. Ghobrial, MD, PhD	Regional Rep. Region 4	X
Johnny C. Hong, MD	Regional Rep. Region 5	
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	
Michael Marvin, MD	Regional Rep. Region 11	X
Tom Mone	At Large	
Kim Brown, MD	At Large	X
Kareem Abu-Elmagd, MD	At Large	
Michael Charlton, MD	At Large	X
James Trotter, MD	At Large	
James Eason, MD	At Large	X
Simon P. Horslen, MB, ChB	At Large	X
Goran B. Klintmalm, MD, PhD	At Large	X
Thomas Starr	At Large	
Fredric G. Regenstein, MD	At Large	
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	X
Ken Murphy	Board Liaison	X
Sandy Feng, MD	Organ Availability Committee	X
James Bowman, MD	Ex Officio, HRSA	X
Monica Lin, PhD	Ex Officio, HRSA	X
Ba Lin, PhD	Ex Officio, HRSA	X
Jon Snyder, MD	MMRF, SRTR Representative	X
Bertram Kasisky, MD	MMRF, SRTR Representative	X
Dorry Segev, MD	MMRF, SRTR Representative	X
Cheryl Hall	UNOS Business Analyst	X
Erick Edwards, PhD	UNOS, Assistant Director of Research	X
Ann Harper	UNOS, Policy Analyst	X
Kim Johnson, MS	UNOS Prof. Services Coordinator	X
Vipra Ghimire, MPH, CHES	UNOS, Policy Analyst	X