

**OPTN/UNOS Pediatric Transplantation Committee**  
**Interim Report: December 9, 2011 Meeting**

**David N. Campbell, M.D., Chair**  
**Heung Bae Kim, M.D., Vice Chair**

*The OPTN/UNOS Pediatric Transplantation Committee (the Committee) met by teleconference on December 9, 2011, to discuss those policy proposals that UNOS distributed for public comment consideration on September 16, 2011. The following summarizes the Committee's discussion for each respective proposal that it discussed.*

1. Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors (Living Donor Committee) - The vice chair of the Living Donor Committee, Amy Waterman, Ph.D., joined the teleconference to present the Living Donor Committee's proposals. After Dr. Waterman presented the proposal, a Committee member asked if a center's informed consent procedure was expected to incorporate the policy language verbatim. Dr. Waterman clarified that the policy provides minimal elements that must be included, but does not necessarily need to be copied exactly. As current transplant center informed consent practices were reviewed in the development of this proposal, it is very possible that centers already have a process in place that complies with this policy. In response to another question, Dr. Waterman clarified that these requirements are only for living kidney donors; however, policy for living liver donors is anticipated in the future.

Without any further questions or discussion, the Committee unanimously voted in favor of the proposal as drafted (14-support, 0-oppose, 0-abstentions).

2. Proposal To Establish Requirements for the Medical Evaluation of Living Kidney Donors (Living Donor Committee) - After Dr. Waterman presented this proposal, a Committee member clarified that these policies aim to establish minimal requirements. Dr. Waterman confirmed that these are minimal requirements that a center must incorporate, but centers could do more evaluation as they deem necessary. Dr. Waterman also indicated that if these policies are adopted, centers would be responsible for these requirements for potential living kidney donors whose initial evaluation begins on or after the implementation date. Those living donors that have already begun the living donor assessment process prior to the implementation date would not be reviewed for compliance with these requirements.

Without any further questions or discussion, the Committee unanimously voted in favor of the proposal as drafted (14-support, 0-oppose, 0-abstentions).

3. Proposal To Establish Minimum Requirements for Living Kidney Donor Follow-Up (Living Donor Committee) - Dr. Waterman proceeded to present the Living Donor Committee's third proposal. A Committee member commented on common reasons why living donors do not participate in follow-up, and questioned what led the Living Donor Committee to recommend a 90% threshold for submission of living donor follow-up forms considering the data regarding the current completion of these forms. Additionally, does the Living Donor Committee have any strategies to recommend reaching this level of compliance? Dr. Waterman replied that compliance with these policies will likely require transplant centers to conduct a focused review of their processes for living donor follow-up, and explore areas for improvement. To help with this centers could refer to best practice guidelines that the Living Donor Committee developed after reviewing the practices and procedures of those centers that have been successful in following-up with living kidney donors. Another Committee member asked what the penalty would be for not reaching this 90% threshold.

Dr. Waterman and UNOS staff explained that the process would be the same as any other potential policy violation.

Committee members appreciated the intent of this proposal, but questioned how raising the expectation for follow-up would necessarily result in obtaining more complete data. This is especially concerning considering those situations where the incomplete information is a function of the donor's lack of interest in participating in the follow-up, not because the transplant center is neglecting its responsibilities. To address such situations, a Committee member recommending including an option that indicates, "follow-up had been pursued but refused," which would be considered complete, compliant data. Additional Committee discussion indicated that this acceptable "follow-up had been pursued but refused" response should only be applied to lab values, or other questions that require donor cooperation to obtain answers. Concerns were raised that this would be hard to audit. Dr. Waterman indicated that the proposal did not currently include such a provision, but that the Committee would welcome feedback to consider. In addition, she reminded call participants that the minimal requirements for informed consent introduce the necessity of living donor follow-up. It is her opinion that if the follow-up expectation is introduced early and its importance is stressed, then better follow-up compliance will likely result.

Another Committee member who would be joining the call late submitted a question for the Committee to consider in case she would not be on the call in time for this discussion: will there be a minimal number of living donor kidney cases required before the 90% threshold would be applied? The Committee member's concern was small volume centers could quickly fall below this threshold with just one incomplete living donor follow-up form (e.g. a center following four living kidney donors with one incomplete follow-up form would result in a noncompliant score of 75%). Dr. Waterman indicated that nothing in the current proposal addressed this situation for low volume centers, and encouraged the Committee to send these concerns to the Living Donor Committee. A Committee member suggested determining a confidence interval for the compliance threshold to consider a center's volume in compliance with this policy.

A Committee member questioned the reliability of the responses that will be provided for the "donor developed hypertension requiring medication" and "diabetes" questions. As these are yes/no questions exploring historical data, and without detailed definitions, the concern is that these questions will not be answered in a consistent manner by living donors due to differing interpretations of the question. Dr. Waterman indicated that this was a valid concern and has been raised by a few parties already.

The Committee supports the concept of the proposal but has a few concerns with what is being proposed:

- The Committee was concerned that a simple 90% threshold could result in centers with small volumes of living donors being out of compliance with just one incomplete form, regardless of the center's diligence in following-up with its living donors (e.g. If the center is following four living donors, one incomplete form yields 75% form completion). To account for this, the Committee suggests determining a confidence interval for the 90% compliance threshold (or some other measure) to consider a center's volume in their compliance with this policy.
- The Committee is also concerned with the difference between current compliance rates and the expectations in this policy proposal. There is concern about members' ability to comply immediately with these requirements. A suggestion to help members' compliance is a progressive increase over a few years in the expected percentage of completed living donor follow-up forms, with the requirement eventually being set at 90%.

- The Committee recognizes that incomplete forms are sometimes because the living donor is not cooperative with the follow-up process. As such, the Committee is concerned with transplant centers being out of compliance in spite of their best efforts. To account for these donors that refuse to participate in the follow-up process, the Committee suggests including a response that would be considered a “complete” answer that indicates that follow-up had been pursued, but declined by the living donor. This response option should only be available for those questions that require explicit donor cooperation, such as obtaining laboratory values.

The Committee unanimously voted in favor of a motion to support this proposal, along with communication of these three concerns and suggestions for the Living Donor Committee’s consideration. (14-support, 0-oppose, 0-abstentions)

4. Proposal to Extend the “Share 15” Regional Distribution Policy to “Share 15 National” & Proposal For Regional Distribution of Livers for Critically Ill Candidates (Liver and Intestinal Organ Transplantation Committee) – The Committee Vice Chair, Heung Bae Kim, M.D., presented the proposal for the Committee’s discussion.

A Committee member asked if the candidate’s calculated MELD/PELD score or MELD/PELD score including exceptions would be used for this allocation algorithm. If “Share 15 National” uses scores with exceptions, it was predicted that numerous exceptions will be submitted to get a score above 15. Noting that standard exceptions would be included for “Share 35 National,” the Committee was unclear where PELD candidates with scores above 40 would appear on the match run.

A Committee member asked how this allocation change may affect adolescent liver candidates. Discussion indicated that the “Share 35 Regional” changes would benefit liver candidates with elevated MELD/PELD scores, including adolescents. Similarly, those with MELD/PELD scores less than 35, including adolescents, will be lower on the match run. The Committee expressed some concern about adolescents that didn’t have elevated MELD scores, as their generally lower creatinine values result in lower MELD scores. Sensitive to these concerns, other Committee members commented that the magnitude of the impact from these policy changes is probably not great enough to show a significant effect on adolescent candidates.

A Committee member commented that he would be interested in reviewing data that evaluates the survival benefit for those pediatric patients with PELD scores. He continued that analyzing the decrease in total deaths by the average distance instead of the median distance and analyzing the proportion of livers that will travel further than the set distance threshold (e.g. 250 miles, distances that require flight travel). A significant increase in the number of livers traveling an increased distance could be detrimental.

The Committee unanimously voted in favor a motion to support the “Share 35 Regional” proposal, with a request that the Liver Committee clarify how candidates with a PELD score greater than 40 will be prioritized in this allocation algorithm. (14-support, 0-oppose, 0-abstentions)

Additionally, the Committee unanimously voted in favor a motion to support the “Share 15 National” proposal as written. (14-support, 0-oppose, 0-abstentions)

5. Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNet<sup>SM</sup> a Change in

Criterion or Status within Twenty-Four Hours of that Change (Thoracic Organ Transplantation Committee) - UNOS staff presented this proposal for the Committee. After minimal discussion, the Committee unanimously voted in favor of a motion to support the proposal as written. (13-support, 0-oppose, 0-abstentions)

6. 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 (Ad Hoc International Relations and Ethics Committees) - UNOS staff presented the proposal for the Committee. A Committee member from a border state indicated that she thought the policy would be helpful, mentioning current measures in place at her center to keep the transplant rate of non-citizen, US residents below 5%. She felt this proposal would increase these candidates access, but felt it did not adequately address “transplant tourism.” Considering the limited number of donors, she recommended measures be put in place to limit the number of non-citizen, non-resident transplants. Another Committee member expressed concerns about potential negative responses from the public, directed at centers for transplanting patients addressed in the proposal, if data that will be collected is interpreted or presented in a sensational manner. Another Committee member commented on the potential that the questions outlined in the proposal could easily be answered deceptively, and questioned if stricter definitions could curtail this. UNOS staff indicated that this is a concern, and numerous parties have pointed this out.

A motion was made to support the proposal with a request that the Ad Hoc International Relations and Ethics Committees consider including a more comprehensive review process for, or limit the number of, non-US resident, non-US citizen transplants. The Committee voted in support of this motion, with one opposing vote and one abstaining vote. (11-support, 1-oppose, 1-abstention)

7. Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions (Organ Procurement Organization (OPO) Committee) - After minimal discussion, the Committee unanimously voted in favor of a motion to support the proposal as written. (11-support, 0-oppose, 0-abstentions).

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Teleconference**

<b>NAME</b>	<b>COMMITTEE POSITION</b>	<b>Phone</b>
David Campbell, MD	Chair	X
Heung Bae Kim, MD	Vice Chair	X
Laura O'Melia, CPNP	Regional Representative	X
Stephen Dunn, MD	Regional Representative	
Alfonso Campos, MD	Regional Representative	
Jose Almeda, MD	Regional Representative	
Debra Strichartz, RN, BA, CCTC	Regional Representative	X
Andre Dick, MD, FACS	Regional Representative	X
Sharon Bartosh, MD	Regional Representative	
Jeffrey Lowell, MD	Regional Representative	
Kishore Iyer, MD	Regional Representative	
Jeff Shuhaiber, MD	Regional Representative	
Kathy Jabs, MD	Regional Representative	X
Sandra Amaral, MD	At Large	X
Eileen Brewer, MD	At Large	X
John Bucuvalas, MD	At Large	X
Blanche Chavers, MD	At Large	
Shylah Haldeman, RN	At Large	X
Clifford Chin, MD	At Large	X
Carmen Cosio, MD	At Large	X
Alan Farney, MD, PhD	At Large	
Simon Horslen, MB, ChB	At Large	X
Kimberly Hoagwood, PhD	At Large	X
William Mahle, MD	At Large	
Debbi McRann, RN	At Large	
Douglas Milbrath	At Large	
Gary Visner, DO	At Large	
Jerry Wright, RN, CPTC	At Large	
James Bowman, MD	HRSA	X
Monica Lin, PhD	HRSA	X
Ba Lin, MS, MPH	HRSA	X
Wida Cherikh, PhD	UNOS Research	X
Chad Waller, MS	Committee Liaison	X
Jory Parker	UNOS Business Analyst	X
Jodi Smith, MD	SRTR- MMRF	X