OPTN/UNOS ETHICS COMMITTEE REPORT
MEETING SUMMARY
August 11, 2009
4:00 p.m. – 5:00 p.m. EDT

Michael Shapiro, M.D., Chair
Alexandra Glazier, J.D., MPH, Vice-Chair

The following report represents the Ethics Committee's deliberations and discussions at its meeting held by conference call on August 11, 2009:

1. Update on Principles of Allocation White Paper. Dr. Shapiro reported on the prior attempt to present the Committee's Principles of Allocation white paper to the Board of Directors at the Board's June 2009. Dr. Shapiro communicated this to the Committee that HRSA had decided that the paper should not be presented to the Board of Directors. It is the current understanding that HRSA is concerned that there would potentially be a document that could be interpreted as competing with the OPTN Final Rule. Concerns were shared that the lack of explanation is concerning, particularly with the significant concessions in language that were made in an attempt to assuage HRSA's previously shared concerns. It was suggested to change the paper back to the originally intended document and to publish it separately as a non-OPTN/UNOS document because it represented important concepts and was a marked improvement from the original 1991 white paper.

Dr. Shapiro recounted some of the history of the development of the document for the new members of the Committee. The existing version of the white paper will be distributed to the full committee for review.

2. Review of Proposal Submitted for Public Comment. The Committee reviewed the following seven (7) proposal submitted for public comment and offers the following feedback to the sponsoring committees:

1) **Kidney Transplantation Committee - Proposal to Include Non-Directed Living Donors and Donor Chains in the Kidney Paired Donation Pilot Program (Affected Program: Kidney Paired Donation Pilot Program).** Currently, the Kidney Paired Donation (KPD) Pilot Program only allows potential living donors with incompatible potential recipients to participate. Potential non-directed (or altruistic) living donors (those who are not linked to an incompatible potential recipient) have no way to enter the program. Also, candidate/ donor pairs can only be matched in groups of two or three, and all donor nephrectomies in the group must occur simultaneously. This proposal would allow potential non-directed living donors (NDDs) to participate in the KPD Pilot Program and add donor chains as an option in the system. A donor chain occurs when a NDD gives a kidney to a recipient whose living donor in turn gives a kidney to another recipient and continues the chain. This proposal would allow two types of donor chains: open and closed. Closed chains start with a NDD and end with a donation to a recipient on the deceased donor waiting list. Open chains start with a NDD and end with a potential bridge donor who will start another segment in the open chain. In open chains, the bridge donor nephrectomy does not occur at the same time as the other living donor nephrectomies. Donor chains have the potential to increase the number of transplants in a KPD system.

a) Ethics Committee Comment: It was noted that an open chain leaves a donor and that it is preferable to have the donations occur simultaneously. If an altruistic donor is entered at the beginning, then it is open ended, with a committed but not yet donated donor at the end of the chain. There is no way when one is left with the bridge donor (Donor C), to ensure that the donor ultimately donates. They cannot be forced to make the donation. Concerns were shared

about the size of the grouping and the points assigned based upon the size of the groupings.

b) It was also suggested that if a chain starts with a blood type O donor and at the end of the line, there is the option of giving it to an A candidate or a B candidate, then preference should be given to a B candidate because they are disadvantaged blood groups.

c) It should be noted that altruistic donors are uncommon, particularly when used as the start of an open ended chain. It was noted that the Resource Document for the Medical Evaluation of Living Donors is being suggested as a standard for evaluation in the nature of a formal Policy, but without going through the policymaking process.

d) It was questioned about maintaining the confidentiality of medical records and information for donors in these paired donations.

e) The Committee also discussed whether the quality of organs should be weighed by the donor pairs. For example, should an individual whose paired donor donates a 60 year old kidney to the chain be able to receive a kidney donated from a 20 year old donor kidney, that was donated to the chain?

f) What if the donor for the paired recipient wants to put restrictions on the recipient of their donor kidney? How should their autonomy be weighed?

g) It was asked why it is necessary to ask whether a donor would consider being a bridge donor? Is there a potential that putting the statement in the questionnaire creates a coercive environment for the donor in the context of increasing the possibility that the intended recipient would receive a kidney?

2) **Living Donor Committee - Proposal to Improve the ABO Verification Process for Living Donors (Affected Policies: Policy 12.3.1 - ABO Identification; Policy 12.8.1. - Reporting Requirements).** This policy proposal improves the safety of living donation through an improved ABO verification and matching process. Currently, the ABO verification and matching requirements for living donors are less stringent than the requirements for deceased donors.

a) Ethics Committee Comment: The Ethics Committee reviewed the proposal and determined that there was no specific ethical issue requiring comment.

3) **Living Donor Committee - Proposed Guidance for the Medical Evaluation of Living Liver Donors).** This resource is a voluntary set of recommendations for OPTN member transplant hospitals to use when developing their program-specific living liver donor medical evaluation protocols. This resource is not a policy or a bylaw. The OPTN contractor will not monitor adherence to these guidelines.

a) Ethics Committee Comment: The Ethics Committee reviewed the proposal and determined that there was no specific ethical issue requiring comment.

4) **Membership and Professional Standards Committee - OPTN Notification Requirements for OPOs, Transplant Hospitals, and Histocompatibility Labs When Faced with an Adverse Action Taken by Regulatory Agencies (Affected Bylaws: Appendix B (Sections I, II, III): Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership).** The purpose of this bylaw modification is to clarify member responsibilities with regard to OPTN notification of adverse actions taken by regulatory agencies that would impact the organizations ability to serve transplant patients. The Committee modified existing language within the bylaws to clarify material submission and extend time periods for action.

a) Ethics Committee Comment: The Ethics Committee reviewed the proposal and determined that there was no specific ethical issue requiring comment.

5) **Membership and Professional Standards Committee - Proposal to Change the UNOS Bylaws to Reconcile Discrepancies in Patient Volume Requirements for Full and Conditional Program Approval When Qualifying Kidney, Liver and Pancreas Primary Transplant Physicians (Affected Bylaw: Appendix B, Attachment I)** This proposal will reconcile the current patient volume discrepancies between the requirements for full and conditional OPTN/UNOS program approval when qualifying primary physicians at kidney, liver and pancreas transplant programs. The bylaws currently permit programs to propose and qualify primary physician candidates for conditional program approval without meeting the MPSC desired 50% of full approval primary care volume requirements when submitting their application. The primary physician at the conditionally approved program can then qualify that program for full approval status after one year at conditional approval without ever having met the same total patient volume requirements as the primary physician originally qualifying at a fully approved program. The proposed language does not change any prior Board approved total patient volume requirements used to qualify for full program approval as the primary physician at kidney, liver and pancreas transplant programs when using either experience or training pathways. Additionally, it clarifies the initial minimum required patient volume to qualify a candidate for consideration as the primary kidney, liver or pancreas physicians at a program seeking conditional approval.

a) Ethics Committee Comment: The Ethics Committee reviewed the proposal and determined that there was no specific ethical issue requiring comment.

6) **Membership and Professional Standards Committee - Proposal to Add Language to the OPTN/UNOS Bylaws Requiring Transplant Center and OPO Members to Follow State Law Regarding Anatomical Gifts (Affected Bylaws/Policy: Article I, Sec 1.10, Appendix B, Section I and II, and Policy 3.4: Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation).** This proposal adds language to the bylaws stipulating that members are obligated to follow their respective state laws regarding anatomical gifts. This bylaw will ultimately help preserve public trust in the national organ transplant system by preventing conflicts of interest associated with having the same person declare death and perform organ procurement and transplantation. The ultimate goal of this proposed change is to prohibit the same physician from declaring a patients death and participating in the removal or transplant of organs from that decedent.

a) Ethics Committee Comment: The Ethics Committee reviewed the proposal and determined that there was no specific ethical issue requiring comment.

7) **Organ Procurement Organization (OPO) Committee - Proposal to Change Requirements for Labeling and Packaging Organs Procured by Visiting Transplant Center Teams and for OPO Labeling of Tissue Typing Materials (Affected Policy: Policy 5.0 Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials (Organ Procurement Organization) (OPO) Committee)** The Committee is seeking comment on two proposed modifications to Policy 5.0. Current policy assigns responsibility for packaging and labeling of organs to the OPO. In certain situations, recovery teams may arrive from transplant centers to procure hearts and lungs. Due to the effects of prolonged cold ischemic time on these organs, these recovery teams sometimes forgo the labeling procedure, which leaves the OPO out of compliance with Policy 5.0. The proposed modification to Policy 5.0 transfers the responsibility of packaging and labeling of organs to the transplant center when its recovery team elects to recover organ(s) and transport the organ(s) directly to their transplant center for transplant. This should be done in collaboration with the OPO. Additionally, current policy requires that tissue-typing material containers be labeled with one unique identifier. The Joint Commission (JC) requirements for accreditation

stipulate that tissue-typing material be labeled with two unique identifiers. This proposal seeks to realign OPTN policy with JC requirements by changing the requirement from one to two unique identifiers. This modification is anticipated to enhance patient safety while reducing the confusion that members face when attempting to comply with several requirements from different regulatory bodies.

a) Ethics Committee Comment: The Ethics Committee reviewed the proposal and determined that there was no specific ethical issue requiring comment.

The Committee unanimously supported each of the foregoing proposals with the accompanying comments.

Attendance at the Ethics Committee Meeting
August 11, 2009
Conference Call

Committee Members Attending:

Michael Shapiro, M.D.	Chair	
Alexandra K. Glazier, J.D., M.P.H.	Vice-Chair	
Alison Silva, RN, BSN, CCTC		Region 3
Nathalie G. Murray, M.D.		Region 4
Randolph L. Schaffer, III, M.D.		Region 5
Pasala Ravichandran, M.D.		Region 6
Lauris C. Kaldjian, M.D., Ph.D.		Region 8
Richard Demme, M.D.	Region 9	
Robert M. Sade, M.D.		Region 10
Elisa J. Gordon, Ph.D., MPH		At Large
Jack Berry		At Large
Remonia Chapman		At Large
Daniel J. Lebovitz, M.D.		At Large
Liz Lehr, BSN, MHA		At Large
Rachel Mackey		At Large
Lainie F. Ross, M.D., Ph.D.		At Large
Therese Beigay, MA, CPTC, HRSA		*Ex officio*

Committee Members Unable to Attend:

Matthew G. Nuhn, M.D.		Region 1
Melissa J. Doniger, J.D.	Region 2	
Bhargav M. Mistry, M.D.		Region 7
Amy Pope-Harman, M.D.		Region 10
James M. Dubois, Ph.D., DSc		At Large
Ronald E. Domen, MD	At Large	
Robert Mazor, M.D.		At Large
Kevin E. C. Meyers, M.D.		At Large
Dane Sommer, D.Min., BCC		At Large

Board Liaison:
Mark C. Norquist

UNOS Staff:

Jason P. Livingston, Esq.	UNOS