

**Interim Report of the
OPTN/UNOS Operations and Safety Committee**

**September 10, 2009
Chicago, Illinois**

**Chairman – Richard D. Hasz, Jr., MFS
Vice-Chairman – Philip C. Camp, Jr., MD**

The Operations Committee met on September 10, 2009, and considered the following items:

1. Policy Items

- Removal of Liver Candidates within 24 Hours of Transplant – The Committee reviewed additional data regarding member compliance with the 24-hour removal policy. The findings indicate increased compliance with the policy over the last five years for all organs. Since the same policy language is present in each of the organ-specific versions of policy, the Committee had previously formulated proposed policy modifications for Policies 3.6.6, 3.2.4.1, 3.7.14 and 3.8.7 that would change 24 hours to one working day. This proposed modification was circulated to three organ-specific committees for feedback. The Committee decided to refrain from moving forward with the policy modification and continue to review policy compliance data over the next six and 12 month periods.

Operations and Safety Committee vote: 13 - For, 0 - Opposed, 0 - Abstentions

- Blood Group A Sub-typing – The Committee continued its review of blood group A subtyping data for both deceased and living donors to attempt to quantify the risk of an incorrect ABO subtyping occurring. OPTN policy does not require the same standards for subtyping as it does for ABO typing. Therefore, Committee recommends that subtyping must meet the same standards as ABO typing for patient safety and consistency and believes double verification should be mandatory for blood group A subtyping for both living and deceased donors with two separate typing instances required. In the event two separate typing instances cannot be obtained or the subtype cannot be verified or validated, the blood type must be recorded as an A blood group as a patient safety precaution. The Committee further recommended that Unetsm and DonorNet® support the function of double verification of ABO typing and subtyping and verification. A working group will formulate proposed policy modifications and review existing policies to ensure proper modifications are suggested.

Operations and Safety Committee vote: 19 - For, 0 - Opposed, 0 - Abstentions

- National Pancreas Allocation System – Elizabeth Sleeman, UNOS Liaison to the Pancreas Committee, provided an overview of new concepts for pancreas allocation. Operations and Safety Committee comments were that the Pancreas Committee may wish to consider re-evaluating pancreas islet requirements as some believe that high BMIs do not necessarily correlate to a fatty pancreas and that the pancreas list should be exhausted before islets are allocated. Several committee members believe that combining the list for ease of use, allocation, and increased utilization of the pancreas should be supported.
- Consideration of Public Comment Proposals – The Committee considered current proposed policies, which were included in the Public Comment document dated July 10, 2009. The Operations and Safety Committee's opinion is shown below for the selected proposals the Committee considered within its purview:

- Proposal to Improve the ABO Verification Process for Living Donors Affected Policies: Policy 12.3.1 - ABO Identification, Policy 12.8.1 - (Reporting Requirements). The Committee supports this proposal to promote safety and consistency while suggesting that ABO subtyping be added to this proposal.

Operations and Safety Committee Vote: 18 For - 0 Against - 0 Abstention

- Proposal to Add Language to the OPTN/UNOS Bylaws Requiring Transplant Center and OPO Members to Follow State Law Regarding Anatomical Gifts - Policy/Bylaws affected: Bylaws, Article I, Section 1.10 (Member Obligations), Appendix B to Bylaws, Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership, Section I (Organ Procurement Organizations) and Section II (Transplant Hospitals), Policy 3.4 (Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation). The Committee agrees with the addition of “surgical or operative” preceding procedure in the proposal. An example where the pronouncing physician may be asked to re-intubate the donor was cited. It was asked if this proposal might potentially impact small, rural donor hospitals. To this point there has been no feedback to indicate this is the case. The UAGA cover this and they should be in compliance already. The Committee did discuss DCD donor situations where anesthesia will not pronounce the donor dead in the operating room. There was some discussion regarding who would be pronouncing the donor dead in the operating room. If there is not an attending of record, or their designee, in the operating room and anesthesia is not going to pronounce, the Committee was concerned that the transplant surgeon might be asked to pronounce. DCD protocols need to clarify these situations.

Operations and Safety Committee Vote: 18 For - 0 Against - 0 Abstentions

- Proposal to Change Requirements for Labeling and Packaging Organs Procured by Visiting Transplant Center Teams and for OPO Labeling of Tissue Typing Materials. - Policy affected: Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials). The Committee does not support the proposal as written. The Committee does not support the shift of responsibility to the transplant center (recovery team) from the OPO. The majority of the Committee views the responsibility for packaging and labeling deceased donor organs as a mutual duty or obligation of the OPO and transplant center in order to ensure patient safety. Some Committee members believe a shared or mutual duty or responsibility is too vague in terms of how a process gets implemented. Some Committee members were in favor of some formalized crosscheck process with the employment of a checklist with signatures that ensures which organ, what blood type, which preservation solution, what tissue typing materials, etc. are included and properly labeled before any recovery team leaves. The Committee supports reporting of these packaging and labeling violations in the Patient Safety System as a patient safety situation. The Committee realizes that many transplant programs utilize fellows to recover organs and supports promoting following policy as part of the culture and training of these individuals. There is no approved list of secondary unique identifiers that can be employed for a crosscheck on the tissue typing materials. The Committee requests guidance or a list of unique identifiers from which to choose.

Operations Committee Vote: 0 For - 18 Against - 0 Abstentions

The Committee considered current proposed policies, which were included in the Public Comment document dated August 17, 2009. The Operations and Safety Committee’s opinion is shown below for the selected proposals the Committee considered within its purview:

- Proposal to Modify Requirements for Mandatory HTLV-1/2 Testing for All Potential Deceased Donors – Policy affected: Policy 2.2.3.1 (For All Potential Donors). The Operations and Safety Committee voted to support the elimination of prospective HTLV donor testing and not advocate for retrospective testing. The dilemma of what to do with positive retrospective test results was discussed by the Committee and found to be problematic. The Committee suggested that transplant centers may want to discuss this change internally regarding pre-transplant consenting processes.

Operations and Safety Committee Vote: 18 For - 0 Against - 0 Abstentions

2. Patient Safety System

- Refocusing of the Committee – Mary Ellison, PhD, Federal Affairs Assistant Executive Director, provided insight regarding the Committee’s new focus on patient safety. The Committee is tasked with reviewing events reported to the Organ Procurement and Transplantation Network (OPTN) by using a high level systems thinking approach in an effort to apply this way of thinking to the transplant progress and begin to proactively address potential patient safety events.
- Disease Transmission Cases Trends – The Committee reviewed a presentation of disease transmission case reports during the time period of January 1, 2006 to August 31, 2009. Trends of operational issues that resulted in safety events were identified by the OPTN/UNOS Ad Hoc Disease Transmission Advisory committee (DTAC) and referred to this Committee for review. The Committee will address the trends.
- Ad Hoc Disease Transmission Advisory Committee (DTAC) and HTLV I/II Update – Michael Ison, MD, DTAG Chair, provided a presentation regarding the Committee’s current activities including N1H1 and HTLV 1/2. Questions were entertained.
- Operational and Logistical Issues Regarding Possible H1N1 Pandemic Feedback - The Operations and Safety Committee was asked by UNOS executive leadership to assess the potential operational and logistical issues for the transplant system in relation to the H1N1 pandemic. Current policies and bylaws address what to do when members’ infrastructure is devastated or obliterated by disaster and outline the alternatives for conducting business. The Committee believes that a pandemic would be a medical catastrophe and that this situation is not specifically addressed in existing policies and bylaws. Additionally it is believed that there are mechanisms in place to assist members in the event of a regional or local pandemic and that the incapacitating impact is going to be far more of a risk for transplant programs than for the OPOs. The Committee provided recommendations, guidance, and suggestions to UNOS executive leadership.
- Organ Center Transportation Report – The Committee reviewed the Organ Center (OC) four-month transportation report which revealed transportation failures have increased as compared to near misses reported in previous years. The OC will continue to enhance this report to capture additional categories of events.

3. Technology Items

- Tiered Acceptance Working Group Report – UNOS Staff provided summary report of the Tiered Acceptance Working Group that met via LiveMeeting on September 8, 2009. The working group acknowledged that this is a concept worth investigating, programming options will be investigated, and members need to be educated regarding screening criteria that currently exists within DonorNet[®] to with waiting list management. The group has requested to review data to identify clusters of centers in which we can identify philosophies of screening criteria and usage of current tools available, what is the benefit from a tiered acceptance concept related to match run lengths, organ types, ischemic times, reduction of organ wastage, and the dynamics of DonorNet[®] data to access how often data is changing.

Next 2009 Meeting Dates – The Committee will meet on April 15 and September 2, 2010 at O’Hare Hilton Hotel, Chicago.

Operations and Safety Committee Liaisons:

Gloria J. Taylor

Kimberly H. Taylor