

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

**April 15, 2010
Chicago, Illinois**

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

The Operations and Safety Committee met on April 15, 2010, and considered the following items:

1. Patient Safety System and Updates

- Flow of Information – The Committee’s reviewed how information from all safety reporting portals within UNOS gets entered to the Patient Safety Systemsm for the committee’s review.
- Patient Safety Planning Development Group (PSPDG) – Karen Cox, Quality Improvement and Patient Safety committee member, provided information to the committee regarding the current status of the PSPDG’s development of a process by which safety events reported to the Organ Procurement and Transplantation Network (OPTN) will be reviewed by the Committee. The process being developed will allow patient safety staff to collect adequate information regarding reported events in the beginning of the investigation process, assist staff by providing tools to conduct a thorough review, provide information to members on how to conduct a root cause analysis (RCA), and allow for data collection to track trends and patterns in reporting.
- Patient Safety Reports Trends and Patterns – Darren Stewart, UNOS Biostatistician, reviewed patient safety events reported to the OPTN and reviewed by the Membership and Professional Standards Committee (MPSC) in 2009. The Committee discussed the data and agreed to develop a work group to address safety issues related to packaging and labeling of organs and extra vessels which accounted for 55 percent of events reviewed by the MPSC in 2009.
- Ad Hoc Disease Transmission Advisory Committee (DTAC) Update – Michael Ison, MD, DTAC Chair, provided a presentation regarding DTAC’s current activities and disease transmission case reporting trends. Members of the Operations and Safety Committee have participated on a joint working group with the DTAC to address issues related to timely reporting of donor cultures, hemodilution of specimens, and proposed development of patient safety contact for all centers. Questions were entertained.
- Patient Safety Referrals for Review – The Committee reviewed two referral memos from Committee Chairs related to incidences that resulted in a safety report being submitted to the Patient Safety Systemsm. The referrals were addressed by the Committee Chair.
- Organ Center Transportation Failure and Near Miss Report – The Committee reviewed the Organ Center (OC) Transportation Failure and Near Miss Report for the timeframe of August 2009 through January 2010. Details regarding the failures were provided for the Committee’s review. The OC will continue to enhance this report to capture additional categories of events as needed. The Committee discussed that this data should be shared with the Organ Procurement Organization (OPO) Committee for review.

2. Policy Items

- Vessel Recovery, Storage, and Transplant Policy Modification Proposal – Steven Rudich, M.D., presented the Vessel Policy Work Group’s proposed modifications to policy 5.0 regarding vessel recovery, storage, and transplant. The Committee discussed the proposal and requested that the work group consider an alternative to discarding Hepatitis C positive vessels as some committee members were not in agreement with this as a practice. It was also requested by the Committee that the work

group consider requirements specific for labeling of Hepatitis C positive vessels to make these vessels available for the intended recipient for issues related to reconstruction and revascularization.

- Removal of Candidates within 24 Hours of Transplant – The Committee reviewed additional data in all organ populations regarding member compliance with the 24-hour removal policy. The findings indicate a continued increase in compliance with the policy over the last six months. The Committee will refrain from moving forward with policy modifications and will forward this data to the Transplant Administrator Committee (TAC) for consideration. The Committee did not feel that the data revealed a patient safety issue to be addressed at this time.
- Blood Group A Sub-typing – As previously requested by the Committee, an internal work group suggested changes to OPTN policies that would be affected by requirements for second verification testing of ABO subtype in blood group A deceased and living donors. After its review, the Committee recommended that a work group be formed to include experts in the field of blood typing to address issues surrounding timing and logistics of the proposed policy changes for ABO subtyping verification testing. The Committee stressed that the intent of the proposal was always to require that in the event that two separate sub-typings could not be obtained or the subtype could not be verified or validated, the donor 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 subtyping and verification, but that this effort could be undertaken at a later time.

3. Technology Items

- Tiered Acceptance Working Group Report – Darren Stewart, UNOS Biostatistician, provided a summary of the data reviewed since September 2009 by the Tiered Acceptance Work Group. Because of the programming demand related to the group's original work, it has agreed focus on educating members about current screening elements that are available within UNetsm and has changed its name to Effective Screening Work Group. The group plans to create a newsletter for the purpose of educating members on donor and candidate screening as well as kidney minimum acceptance criteria. The newsletter will provide contact information to allow members to ask questions related to the topics. Based on the data reviewed over the past months, the work group will begin its focus on outlier centers within the data for the use of expanded criteria donor (ECD) screening. A survey those centers will be conducted to obtain information regarding the philosophy and understanding of how screening criteria is used within their programs and will provide data on how the center compares in acceptance of ECD organs nationally. Lastly, the work group will review data again after surveys are completed and newsletters have been distributed to see if educational efforts have been effective.

4. Consideration of Public Comment Proposals – The Committee considered current proposed policies, which were included in the Public Comment document dated March 19, 2010. The Operations and Safety Committee's opinion is shown below for the selected proposals considered within its purview:

- Liver and Intestinal Organ Transplantation Committee – Proposed Ohio Alternative Local Unit (ALU). Three Donation Service Areas (LifeBanc, Life Connection of Ohio and LifeCenter Organ Donor Network) are requesting a single, combined new Alternative Local Unit in the State of Ohio. There will be a single waiting list within the ALU for liver allocation.

The Operations and Safety Committee chose not to vote on this proposal, but requests that any specific safety issues identified through public comment be discussed with the Committee for their consideration.

- Liver and Intestinal Organ Transplantation Committee – Proposed OneLegacy Split Liver Alternative Allocation System. OneLegacy and the five liver transplant programs in its donation service area (DSA) are proposing a variance, or alternative allocation system (AAS), to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). This AAS would permit the institution to accept a liver for an acceptable candidate at their institution, split that

liver and transplant one lobe into that candidate (known as the index patient) and then transplant the other lobe into any other medically suitable patient listed at the same institution.

The Committee commented that the policy should be clear about consent of the index and secondary recipient prior to splitting a liver. A member commented that this proposal would bypass other recipients within the region if the index patient consents to split and this should be considered. The Operations and Safety Committee Voted: 14 For – 1, Against – 1, 1 - Abstention.

- Liver and Intestinal Organ Transplantation Committee – Proposed Region 2 Split Liver Alternative Allocation System. Region 2 is proposing a variance, or Alternative Allocation System (AAS), to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). Under this AAS, if a candidate in Region 2 is suitable for a segmental transplant, the transplant center may accept a liver offer and transplant the right lobe of that liver into that suitable candidate (known as the index patient). Then center would then be allowed to transplant the left segment of that liver into another medically suitable patient listed at the same center or at an affiliated pediatric institution.

The Committee commented that this policy needs to be clear that consent of the index and secondary recipient must be taken prior to splitting a liver. There should also be clarification of that all Region 2 were in agreement with this proposal. If all of Region 2 is in agreement with the proposal then the Operations and Safety Committee Votes: 15 For – 0 Against - 0 Abstentions.

- Pancreas Transplantation Committee – Proposal to Develop an Efficient, Uniform National Pancreas Allocation System. The purpose of this proposal is to improve the national pancreas allocation system. This improvement is consistent with the OPTN long-range strategic goals and priorities: to increase geographic equity in access and waiting time to deceased donor organs for transplantation; to maximize capacity of deceased donor organ transplantation; to achieve operational efficiency and cost-effectiveness of implementing and maintaining the organ allocation system.

The Committee offered the following discussion:

- This proposal appears to establish a uniform local pancreas allocation system and not a national pancreas allocation system;
- Please clarify if the kidney/pancreas match can be run before donor HLA becomes available as this can be an issue for OPOs trying to identify a surgeon that will fly out to look at the graft and determine if it's a good for use. A committee member commented that when consent is obtained on the donor, HLA is sent, and allocation is started, but if the OPO has to wait for HLA to come back to allocate the pancreas, then the OPO will go back to allocation meantime the OPO is ready to go to the operating room for other organs there will be a delay for getting pancreas recovery teams. It would be beneficial to be able to run the match prior to HLA availability to allow the OPO to begin to identify and assist with travel arrangements for surgeons that are interested in procuring the pancreas.
- Communication will be vital in cases where the recovering surgeon for a pancreas alone may not like the look of the pancreas at recovery and decline for his patient but another center that has a patient further down the list may accept it for a combined kidney/pancreas recipient to facilitate placement of the pancreas.

The Operations and Safety Committee voted: 15 For - 0 Against – 0 Abstentions.

- Ad Hoc Disease Transmission Advisory Committee (DTAC) – Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events. The proposed modifications are meant to clarify and/or improve current OPO and transplant center requirements for screening for, communicating and reporting all potential or confirmed donor-related disease and malignancy transmission events. These changes are expected to: Help improve patient safety and recipient outcomes by making policy consistent with current clinical testing practices in the organ recovery transplant communities and creating a Patient Safety Contact; Place all content related to donor evaluation and screening into one policy section; Further define and standardize the elements of informed consent and the communication of clinically significant information regarding potential disease transmission events; and Provide a clear, plain language policy format that will be easier for members and other readers to understand and follow.

Operations and Safety Committee Vote: 15 For - 0 Against - 0 Abstentions.

- Histocompatibility Committee – Proposal to Require that Deceased Donor HLA Typing be Performed by DNA Methods and Identify Additional Antigens for Kidney, Kidney-Pancreas, Pancreas, and Pancreas Islet Offers. This proposal would require that OPOs and their associated laboratories perform HLA typing of deceased donors by DNA methods and identify the HLA -A, -B, -Cw, -DR and -DQ antigens before making any kidney, kidney-pancreas, pancreas, or pancreas islet offers.

The Committee commented that allocation from a kidney/pancreas match run may be slowed down if HLA typing is required before the match could be run. This could lead to decreased utilization of pancreata.

The Operations and Safety Committee: 15 For - 0 Against - 0 Abstentions.

- Living Donor Committee – Proposal for the Placement of Non-Directed Living Donor Kidneys. This proposal would establish procedures for the placement of non-directed living donor kidneys. Under the proposal, transplant centers would select the recipient of non-directed living donor kidneys based on a match run.

The Operations and Safety Committee did not vote on this proposal but voiced concerns about the inability of some centers to provide this service for their patients, thus only centers with large resources can provide this type of service and this may be an ethical issue that will bias organ donation since the organ will not be allocated according to a match run for the donation service area (DSA).

- Living Donor Committee – Proposal to Require Reporting of Non-utilized and Redirected Living Donor Organs. These proposals require that the organ recovery center report all instances of: living donor organs recovered but not utilized for transplant; living donor organs recovered but then redirected and transplanted into a recipient other than the intended recipient. These events would be reported through the UNetSM Patient Safety System. If a living donor organ is transplanted into a recipient other than the intended recipient, all required donor and recipient information must still be submitted through Teidi.

The Operations and Safety Committee commented that all organs that are recovered and re-directed, whether transplanted or not, should be reported to the Patient Safety Systemsm for data purposes. Please clarify how re-directed organs are placed based on this proposal.

The Operations and Safety Committee Voted: 15 For - 0 Against - 0 Abstentions.

- Organ Procurement Organization (OPO) Committee – Proposal to Require Use of a Standardized, Internal Label that is Distributed by the OPTN and that Transplant Centers Notify the Recovering OPO when they Repackage and Organ. Current OPTN policy only requires that the external label distributed by the OPTN contractor be used for transporting organs and vessels. This proposed policy change would require OPOs and transplant centers to also use standardized, internal labels that are distributed by the OPTN contractor for organ and vessel transport and for vessel storage. This change will make both internal and external labeling consistent throughout the U.S. The proposal also: requires transplant centers to notify the recovering OPO when they repackage an organ; makes the language consistent by changing the term - provided by the OPTN contractor- to the term -distributed by the OPTN contractor; moves Policy 2.5.6.1 which lists the required documentation that accompanies an organ or vessel to policy 5.5.1. clarifies labeling requirements for vessel storage The goal of this proposed change is to improve patient safety and reduce the number of wasted organs by reducing the number of labeling errors

The Operations and Safety Committee did not have adequate time to the review this proposal and entertain questions or discussion. The Committee Chair requested that the Committee convene a conference call within the next month to review the proposal.

Next 2010 Meeting Date – The Committee will meet on September 2, 2010 at O’Hare Hilton Hotel, Chicago.

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