

**OPTN/UNOS Operations and Safety Committee  
Report to the Board of Directors  
November 8-9, 2010  
St. Louis, Missouri**

**Summary**

**I. Action Items for Board Consideration:**

- None

**II. Other Significant Items:**

- The Committee offered a proposal for public comment that would prohibit the storage of Hepatitis C antibody positive and Hepatitis B surface antigen positive extra vessels. (Item 1, Page 3)
- The Committee reviewed and discussed data, trends, and patterns associated with reported safety events to the Patient Safety System. (Item 3, Page 6)
- The Committee reviewed recommendations for modifications to policy requiring ABO subtyping. The modifications are intended to ensure accurate subtyping determination, and verification. (Item 5, Page 7)
- The Committee reviewed the work of the Effective Screening Work Group and the group's educational initiatives. (Item 6, Page 8)

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OPTN/UNOS Operations and Safety Committee  
to the Board of Directors  
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**Phillip C. Camp, Jr., M.D. – Chair  
Jean Davis – Vice Chair**

*This report represents the OPTN/UNOS Operations and Safety Committee (O & S) on discussions and deliberations during its meeting held in Chicago, Illinois on September 2, 2010.*

1. Vessel Recovery, Storage, and Transplant Policy Modification Proposal – The Committee discussed a transmission of HCV that occurred after a stored HCV antibody positive deceased donor extra vessel was inadvertently transplanted into a living donor liver recipient that was HCV negative prior to the time of the vessel implant. The extra vessel was appropriately labeled per policy, but the transplant center did not recognize that the label indicated the extra vessel to be HCV antibody positive at the time of transplant. In response to this event, the Committee created the Vessel Policy Work Group (VPWG) in fall of 2009 to assess whether current policy had failed to protect the recipient of the extra vessel and to propose safeguards needed to prevent transmission of disease when transplanting extra vessels into secondary recipients.

The Committee reviewed the VPWG's proposed modifications to Policy 5.0 regarding vessel recovery, storage, and transplant that addressed several areas of concern for patient safety identified by the group. Proposed policy modifications were to prohibit storage of HCV antibody positive and hepatitis B (HBV) surface antigen positive extra vessels and to require a verification of ABO, all serology results, container contents, date of expiration and Donor ID with intended vessel recipient prior to implantation. These proposed modifications to policy would also include removal of a requirement for the implanting transplant center to provide detailed explanation when hepatitis positive extra vessels are transplanted into a secondary recipient. In the review of extra vessel procurement practices and other issues related to extra vessel disposition reporting, the work group became aware that many within the transplant community may not have appropriate knowledge regarding the definition of an extra vessel. It was believed that this misunderstanding has led to errors in reporting disposition and documenting use of extra vessels. To increase awareness and understanding of the term "extra vessel," a standard definition was developed by the work group and reviewed by the Committee.

During the work group's deliberations, it was clearly communicated to the Committee that the practice of storing extra vessels could not be ruled out altogether, as extra vessels can be life saving during transplant and reconstruction of vasculature after transplant. Options such as special labeling for HCV antibody positive and HBV surface antigen positive stored extra vessels and requiring a separate storage refrigerator were considered by the work group as requested by the Committee. The work group rejected the idea of requiring a special label for serology positive extra vessels as data have shown that more than 50% of patient safety cases reported to the Patient Safety System (PSS) are packaging and labeling errors. Thus, the work group did not feel that a special labeling system for vessels would be effective to reduce the risk of disease transmission. Transplant administrator representatives on the work group also rejected the idea of a separate storage refrigerator stating that it would be a costly and cumbersome system for transplant centers to implement and monitor compliance.

To understand how many potential patients would be affected by prohibiting the storage of HCV antibody positive and HBV surface antigen positive extra vessels, the Committee reviewed data on the number of vessels that were recovered and sent by organ type and how many of the donors vessels procured were HCV or HBV positive during the years of 2008-2009 (**Exhibit A**). The data show that only 2.6% of extra vessels recovered were from HCV antibody positive donors and only 0.1% from HBV surface antigen positive donors. The percentage of recovered vessels with positive hepatitis serologies is slightly higher for livers. There were four HCV antibody positive extra vessels and no HBV surface antigen positive extra vessels transplanted into secondary recipients during this timeframe. Of the four HCV antibody positive extra vessels transplanted, one resulted in a confirmed HCV transmission to a secondary recipient.

The work group did not consider eliminating storage of HBV core antibody positive extra vessels. Based on a literature review, the group determined that these vessels do not involve a higher concern for disease transmission as studies have shown that some organs, other than the liver, procured from HBV core antibody positive donors have been safely transplanted into recipients with minimal risk for transmitting HBV. It was discussed that HBV core antibody positive livers have been shown to transmit hepatitis disease but the rate of re-infection to the recipient can be reduced and outcomes have improved with the use of anti-viral treatments.

Work group representatives reported to the Committee that liver, kidney, and pancreas transplant surgeon representatives on the group agreed that other options are available for use as vascular conduits but are highly inferior or suboptimal compared to a donor's extra vessels, as synthetic conduits have higher rates of thrombosis. It was also stated that many extra vessels procured from deceased donors are unusable due to atherosclerosis so there should not be an assumption that all extra vessels that are stored are useable when needed for transplant or reconstruction of vasculature.

To evaluate the potential impact on extra vessel availability for patients receiving organ transplants from donors that are HCV antibody positive and HBV surface antigen positive (e.g., HCV antibody positive recipient receiving a HCV antibody positive liver) a supply and demand analysis was performed (**Exhibit B**). The analysis evaluated whether enough extra vessels would be available – if storage of HCV antibody positive or HBV surface antigen positive extra vessels storage was prohibited – to meet the needs of recipients of HCV antibody positive or HBV surface antigen positive organs, who may require post-transplant vascular reconstruction. It tabulated the number of times vessels were sent to each transplant center and DSA (the supply), and the number of liver, pancreas, kidney/pancreas, and intestine transplants using HCV antibody positive or HBV surface antigen positive organs (the potential demand), and assumed that there were no acceptable substitutes for donor vessels for vascular reconstruction. Based on the analysis, approximately ten donation service areas (DSA) would likely experience such a shortage. However, while extra vessels are most frequently used during liver, pancreas, or intestine transplant, the vessel policy work group considered anecdotal evidence and estimated the probability of requiring stored extra vessels for vascular revision post-transplant (within 14 days) to be about 1% to 5%, and agreed to a conservative upper estimate of 10%. By incorporating this 10% estimate into the analysis, along with the data on supply and demand for extra vessels across donation service areas (DSA), the number of DSA's likely to experience an "actual" vessel shortage dropped to approximately one.

The Committee agreed with the vessel policy work group's analyses and that the benefit to patient safety, by decreasing the risk of disease transmission from a stored extra vessel, outweighed the occasional but rare extra vessel shortage requiring the use of a donor extra vessel shared from another DSA or the use of a synthetic vessel substitute. The Committee supported moving this proposal forward for public comment. The Committee voted: 17 in favor, 1 opposed, and 0 abstentions.

2. Ad Hoc Disease Transmission Advisory Committee (DTAC) Update – The Committee was provided a presentation regarding DTAC’s current activities and disease transmission case reporting. The DTAC completed its semi-annual review of potential disease transmission events reported to the PSS, discussed policy 2.0 and 4.0 revisions that were recently submitted for public comment, and discussed trends and patterns in case reporting.

The DTAC representative reported that there had been significant increase in reporting potential disease transmission events over the past few years. In 2006 there were only seven reports, last year there were 152 reported events, and this year it is projected that there will be approximately 160 reported potential transmissions for the committee to review. There have been 146 reports of potential transmission of malignancies since 2006. Twenty two have been confirmed as being transmitted to at least one recipient, ten of these events have been associated with patient death as a result of transmission of lymphoma or lung cancer. Infections reported are 201 in total with 106 confirmed and 29 associated recipient deaths since reporting began. Most of the reported deaths in this case are related to viral transmissions. There have been two well recognized transmissions of human immunodeficiency virus (HIV) and hepatitis C virus (HCV). DTAC review has assisted in confirming three HCV transmissions that have been associated with eight recipients being infected and two deaths. West Nile Virus (WNV) and others such as Parvo B19 virus have also been associated with transmission of disease from donors to recipients. Data records reveal 38 reports of potential bacterial disease transmissions with 28 confirmed and seven associated deaths. Thirty fungal transmissions are recorded mostly of endemic mycosis such as cryptococcus. Mycobacterial and parasitic infections have also been reported with associated transmissions and death in recipients of organs. In past years, potential transmissions of Strongyloides have been very concerning to the DTAC. In 2010 there have been several cases of indiscriminate use of encephalitic donors in which the cause of encephalitis goes undiagnosed prior to procurement of organs. Most recently this is highlighted in a confirmed case of Balamuthia transmitted from a donor to recipient. The issue of undiagnosed disease continues to be a significant contributable factor in transmissions. DTAC reviewed all cases from the years 2006-2008 to determine a clear rate of transmission with associated death. The incidence of disease transmission is being estimated at about 0.5% as of 2009 cases reviewed.

The Malignancy Subcommittee of the DTAC has written a document for the community to guide them in the use of organs with associated malignancies. The majority of malignancy potential transmission cases reported are renal cell carcinomas (RCC). There is vast variability in utilization of organs with identified RCC. This wide variability suggests to the subcommittee that guidance and education could be helpful as literature and data do show that RCCs that are small, resected, and only found in one kidney, can be used with minimal risk of transmission in the recipient. The subcommittee has addressed this concern and other issues similar by developing a comprehensive risk stratification system including guidance on care based on donor risk but deferring all clinical decisions to transplant centers. The plan is to publish this manuscript in a major medical journal in the near future.

In review of bacterial, tuberculosis, fungal and viral cases reported to the PSS over the past year, themes that are operational in nature have been identified. DTAC continues to be concerned about the communication challenges between Organ Procurement Organizations (OPO) and transplant centers in notification of disease transmission events. The problem is that there is no standard process in place for these types of notifications within our transplant system, no standard for follow up of recipients, and education needs to be done to teach clinicians what to look for when a disease transmission is expected.

3. Patient Safety Trends and Patterns – The Committee discussed how data flow through the transplantation system from pre-transplant to post transplant activities and how data related to identified safety events are reported to the OPTN. It was discussed that there are multiple portals in which safety events are reported to the OPTN but all of this information has to be compiled into one data system to begin to analyze the data and assess for trends and patterns. In preparation for the review of trends and patterns data, the Committee separated into groups to review case studies of four types of patient safety events that have been reported to the PSS (i.e. disease transmission events, packaging and labeling errors, ABO subtyping errors, and communication errors leading to a near miss or close call). After this exercise was complete, the Committee discussed the process of how centers report, investigate and develop action plans to address the safety concerns identified within their institutions. It was agreed that the Committee could provide reference materials to assist centers in conducting a thorough root cause analysis of safety events, develop a method to disseminate outcomes of safety events to the community, and discuss implementing a patient safety newsletter to periodically highlight safety concerns identified through data review.

UNOS staff reviewed with the Committee data of patient safety events reported to the PSS during the timeframe of August 15, 2008 and August 17, 2009 (**Exhibit C**). These data were previously reviewed at the Committee's April 2010 meeting in which specific areas of concern for safety within the system were identified. Fifty-five percent of the events reported were packaging and labeling complaints or errors, 19 percent were related to inaccurate serological reporting or potential disease transmission, 10 percent were related to data entry errors, and 16 percent were other such as communication errors and surgical errors. Some of the events fell into multiple categories. To assess for trends within the data, UNOS staff graphed the data into trend charts to assist in identifying key events that may have effected reporting during a given period of time. This was an effort to begin assessing cause and affect (i.e. how policy modifications or implementation of resource documents may affect reporting). The Committee discussed options for analyzing the data by DSA, event type, and category to assess for benefit in identifying trends.

4. Packaging and Labeling Errors – The Chair reviewed with the Committee data discussed during the April 2010 meeting showing that 55% of cases reported to the PSS were packaging and labeling errors. Packaging and labeling policies were reviewed along with data on the number of errors identified with these processes during site surveys between the years of 2007-2009 (**Exhibit D**). The Committee then reviewed the OPO Committee's proposed labeling system and checklist that is aimed at making the labeling process more efficient and error free. The OPO Committee conducted a pilot study with the new labeling system and checklist during the timeframe of January 2010 through March 2010. Five OPOs ranging in size with demographic and geographic variables participated in the pilot. Once the pilot was complete, changes were made to the new labeling system based on recommendations from the participants. The OPO Committee received feedback on the proposal during the Spring 2010 public comment period and educational sessions held in August. Based on public comment and feedback from the pilot study and educational sessions, the OPO Committee is planning to take this new labeling system to the Board for approval in November 2010.

The Committee discussed that the new labeling system included an external and an internal label for each organ. The internal label is not currently required by policy until the Board reviews and approves the proposal in November. It was discussed that OPOs currently create their own internal label or elect to use the one created by UNOS. The proposal that will go before the Board will make the internal label standard throughout the United States. In the new labeling system, each organ has its own assigned color for both internal and external labels and a label for extra vessels is also proposed as part of this new system. The extra vessel label contains all pertinent information required by policy and is to be attached to the outermost barrier in which the vessels are packaged. As required by current policy, all serologies are located on the proposed label. An "other" field was added to the

extra vessel label for tests that an OPO may perform that are not required by policy (i.e. HTLV or Chagas testing). The Committee was concerned that the verification form was not required as part of this proposal, but understood that it would be available for use to fulfill policy requirements should an OPO wish to use it. It was discussed that current policy would require each OPO to retain documentation of the verification of accurate labeling event if they choose not to use it the developed checklist.

The Committee agreed that the types of errors reported to the PSS may decrease with the implementation of the new labeling system and the use of the verification checklist. It was discussed that to assess the effectiveness of the new labeling system, the OPO committee will need to identify whether the verification checklist was used in conjunction with the new labeling system. For each error that is reported to the PSS, the analyst inquiring about the event could ask the member to submit a copy of the checklist or their documentation of their verification process as required by policy. This would help to assess whether the checklist should be required in the future. The Committee agreed that data related to the effectiveness of the new labeling system should be reviewed at least six months after the system is implemented.

5. Recommended Policy Modifications for ABO Subtyping Requirements – The Committee reviewed the most common errors, identified through site surveys that were associated with ABO verification and subtyping. After the brief review, the Committee reviewed the ABO Subtyping Work Group’s suggested modifications to policy requiring that subtyping should be performed for all A and AB living and deceased donors. The proposed modifications stated that when initial subtype testing confirms A<sub>2</sub> or A<sub>2</sub>B a second subtype verification test should be completed to ensure the accuracy of the typing. The work group proposes that subtype testing should only be performed on pre-transfusion specimens. When two pre-transfusion specimens are not available for subtyping the organ should be allocated as A or AB for patient safety. The work group also feels strongly that subtype verification should be electronic in DonorNet<sup>®</sup> for deceased and living donors to ensure the safety of the recipients of subtyped organs. This would also require that two separate tests are verified by two separate staff within DonorNet<sup>®</sup> as this is consistent with the way ABO typing is currently verified within the system. The work group also recommends that all organ and vessel labels should include subtyping information when applicable for the organ or vessel. The work group continues its efforts to understanding laboratory proficiency testing and/or certification to perform ABO subtyping, what is the acceptable terminology that denotes current practice with ABO subtyping (i.e. non-A<sub>1</sub> vs. A<sub>2</sub>), and is considering whether requirements for subtyping for very young donors (less than 2 years of age) should be recommended for consideration by the Pediatric Transplantation Committee.

The Committee reviewed feedback received from the Living Donor Committee (LDC) on proposed modifications to living donor policy that would ensure that living donors received the same protections for ABO and subtype verification as deceased donors. The LDC agreed that living donors that are subtyped should have confirmation of that subtype with a second test result but requirements should not imply that the living donor must be subtyped. The LDC explained that many living donor programs do not transplant A<sub>2</sub> donors into O recipients or A<sub>2</sub> donors into B recipients and to make subtyping mandatory in these cases would not be inappropriate and an unnecessary expense with increased administrative burden. It was further explained that some living donor institutions may not have subtyping available as an option at their institution.

The ABO Subtyping Work Group will continue to refine recommended policy modifications based on feedback from other committees and will hope to have a proposal ready for spring public comment for approval by the Committee.

6. Effective Screening Working Group (formerly Tiered Acceptance) – The Committee reviewed a summary of the Effective Screening Working Group’s focus and planned education to members regarding the effective use of screening criteria that are currently available within UNet<sup>SM</sup>. A webinar will be held on September 24, 2010, to increase understanding of screening criteria and awareness of how to use existing UNet<sup>SM</sup> screening tools. The webinar is anticipated to increase motivation for centers to use these screening tools to improve organ placement efficiency. The work group plans to create a newsletter, after the webinar takes place for the purpose of education members further on candidate and donor screening and will allow members to ask questions related to the content. At the end of this process a survey will be sent to a select number of centers to obtain information regarding their philosophy and understanding of how screening criteria is used within their institution. After these efforts are complete, the work group will review data again to see if these educational efforts have been effective and have improve efficiency in placement of organs.
7. DonorNet<sup>®</sup> Abbreviations - The Committee reviewed recommendations from the Transplant Administrators and OPO Committees to standardize abbreviations entered into DonorNet<sup>®</sup>. The Committee believes this to be an appropriate and much needed step in the right direction to standardize processes and documentation that will assist members in clearly communicating important transplant related information to patients and caretakers. It was agreed by the Committee that this type of standardization will promote consistency, efficiency and most importantly, patient safety.

**OPTN/UNOS OPERATIONS COMMITTEE MEETING ATTENDANCE**

<b>Name</b>	<b>Position</b>	<b>Chicago, Illinois September 2, 2010</b>
Phillip C. Camp, Jr., MD	Committee Chair	x
Jean Davis	Committee Vice Chair	x
Sharon Bartley, MS, RN	Region 1 Representative	x
Barbara Turci, RN, BSN, CPTC	Region 2 Representative	x
Michael Angelis, MD	Region 3 Representative	x
Jaymee S. Mayo, RN, BSN	Region 4 Representative	x
Nance D. Conney, BS	Region 5 Representative	x
Kathy Jo Freeman, RN, MSN	Region 6 Representative	x
Julie K. Heimbach, MD	Region 7 Representative	x
Zoe Stewart, MD	Region 8 Representative	x
Theresa M. Daly, MS, FNCP	Region 9 Representative	x
Andrea Martinovich, RN, BSN	Region 10 Representative	x
Jerita Payne, APRN, BC	Region 11 Representative	x
Karen R. Cox, PhD, RN	At Large Representative	x
Stacey L. Doll, MPA	At Large Representative	x
Daniela P. Ladner, MD	At Large Representative	x
J.T. Rhodes, CPA	At Large Representative	x
Michael Ison, MD	At Large Representative	x
Anton Skaro, MD, PhD	At Large Representative	
Sharon E. Swofford, MA, RN, CNN, CCTC	At Large Representative	By Phone
Janel N. Tedesco, ACNP, CCTC	At Large Representative	By Phone
Donna Woods, EdM, PhD	At Large Representative	x
Michael Hagan, DO, MHSA, CMQ	Visiting BOD Member	x
Robert W. Walsh	Ex Officio/HRSA	x

**UNOS staff attending:**

Mary D. Ellison, Ph.D., Assistant Executive Director, Federal Affairs  
 Lin McGaw, RN, MEd, Director Professional Services Department  
 Brian Shepard, Director of OPTN Board and Committee Operations  
 Darren Stewart, Biostatistician, UNOS Research Department  
 Kimberly Taylor, RN, Patient Safety Specialist, Committee Liaison