

OPTN/UNOS Operations and Safety Committee
Report to the Board of Directors
June 28-29, 2011
Richmond, VA

Summary

I. Action Items for Board Consideration

- The Board is asked to approve modifications to Policy 5.10.1 (Vessel Recovery and Transplant) and Policy 5.10.2 (Vessel Storage) that would limit the use of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels to the intended recipient and would require a time out prior to implant of vessels to ensure compatibility between the donor and recipient. (Item 1, Page 3)
- The Board is asked to approve a guidance document on ABO subtyping of blood group A and AB donors. (Item 2, Page 6)

II. Other Significant Items

- The Committee reviewed recommendations for modifications to policy requiring ABO subtyping currently out for public comment. These modifications are intended to ensure accurate subtyping determination and verification. (Item 2, Page 6)
- The Committee reviewed and approved for distribution a quick reference guide to patient safety reporting within the OPTN, and a newsletter created by the Patient Safety Planning Development (PSPD) subcommittee. (Item 3, Page 7)
- The Committee reviewed and discussed patient safety data, trends, and patterns as reported to the OPTN. (Item 4, Page 8)
- The Committee reviewed the work of the Effective Screening Work Group (ESWG) and its educational initiatives to the community over the past six months. (Item 5, Page 8)

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**Report of the
OPTN/UNOS Operations and Safety Committee
to the Board of Directors
June 28-29, 2011
Richmond, Virginia**

**Phillip C. Camp, Jr., M.D. – Chair
Jean Davis – Vice Chair**

This report represents the OPTN/UNOS Operations and Safety Committee's (OSC) discussions and deliberations during its meeting held in Chicago, Illinois on April 7, 2011.

1. **Vessel Recovery, Storage, and Transplant Public Comment Review** – The Committee considered public comment feedback to the proposal put forth for public comment in November 2010 related to vessel recovery, storage, and transplant. After review of the comments, which seemed to have common themes from individuals in the community, committees, and regions, it was agreed that any recommendations to the Board must be based on operational and safety principles. The Committee did not feel that there was clear data on whether it would be safest to store vessels for intended recipients with additional labeling requirements, as current data shows packaging and labeling errors are already a problem. Data that would identify continued issues with the labeling system implemented by the OPTN in January 2011 will not be available until the new process has been in place for six months. It was discussed that OPOs have significant training and expertise in packaging and labeling of organs and vessels and for the most part transplant centers do not have this expertise. Therefore creating a new labeling system for a small subset of vessels could create a situation in which there are more errors. Labeling and documentation best practices would need to be provided for the community should additional labeling requirements for these vessel types be proposed. The committee requested to review data any packaging and labeling events reported to the OPTN after the new labeling system went into effect at its September 2011 meeting.

One major concern highlighted in public comment was the issue of potential vessel shortage. The data analysis completed during the development of this proposal did show that there would be a potential for one to two episodes of vessel shortages within any given donation service area (DSA) within a one year period of time, but the analysis assumed that there would sharing of vessels by transplant centers within the DSA as is currently allowed by policy. In some areas that could be a valid assumption but in others, due to geographical location, this assumption may not be valid. The Committee discussed that data reviewed during the development of the proposal showed 15-20% of liver donors do not have extra vessels recovered and sent with the organ. These could potentially be a supply of vessels that are currently not procured and stored and would decrease the likelihood of a shortage. Surgeons on the Committee responded that when vessels are not recovered most often it is because they are not appropriate for transplant due to calcification or thrombosis.

The likelihood of disease transmission from the transplant of an extra vessel into a secondary recipient, as indicated by the analysis, was difficult to ascertain because there is no data to access the success of a new labeling system at this time. The Committee did discuss that OPTN data could not predict the possibility of a person reaching into a refrigerator and obtaining a vessel that is not compatible with the intended recipient. It also could not predict whether adequate checks would be performed to assess for compatibility prior to transplant of the vessel. It was noted that the transmission event that started these discussions happened despite appropriate labeling of a hepatitis C antibody positive vessel. The proposal distributed for public comment included a requirement for a time out prior to implanting a vessel, which is currently not a process that is standard within the community. To enforce this requirement alone could effectively address the potential for transmission

without restricting the storage of hepatitis positive vessels, as public comment did not appear to agree with this restriction. Surgeons on the committee discussed that lack of vessel availability has the potential for a recipient death and other conduits are not ideal, although these types of instances are rare. It was agreed that inadvertent transplant of a hepatitis positive vessel was not an ideal outcome, but it was also not a death sentence as in the case of not having a vessel available for reconstruction post transplant. It was also noted that small volume centers in an area of high hepatitis C infected patients would feel the greater burden of vessel shortage.

A member shared that representatives from Region 4, during the regional presentation of this proposal, were adamant that this proposal not move forward. This region did not want to hear about the data as they shared that one instance in which there were no vessels available for transplant would be one too many. Another member shared that the regional meeting in Region 8 also had much discussion about this proposal and even though it passed there was a lot of disgruntled surgeons that had a real problem with this policy. Most of the comments were related to implementing a time out was sufficient and not to restrict storage of vessels. It was mentioned that members at the Region 9 meeting believe that they are in an area where there are more hepatitis C positive recipients and there are often situations in which these patients need reconstruction to save the graft and this region does not share vessels due to the need to have them available for this patient population. Representatives at the meeting were in favor of the time out and having two staff members perform the double check.

The Committee discussed the February 2011 publication of the Centers for Disease Control and Prevention's (CDC) MMWR that outlined recommendations for the practice of storing and transplanting vessels from hepatitis positive donors. A member commented that it would be high risk for centers not to implement the recommendations from a public health agency and should a transmission occur the risk to that center could be detrimental. Another member reminded the Committee that the CDC makes recommendations based on a global perspective and may not have considered specific limitations that transplantation poses. The CDC would rather see zero transmission of disease, which may not be possible in organ transplantation. Transplant surgeons on the committee agreed that they would not accept the risk of death for a patient that has already received a transplant because vessels were not available for reconstruction or revascularization when needed. The safest approach is to meet the needs of both sides by implementing a time out procedure and limiting the hepatitis positive vessel to the patient for which it was procured. This approach will avoid sero-positive vessels being transplanted into a sero-negative patient and avoid a shortage of vessels for patient populations that may require vessels after the time of the initial transplant.

It was discussed that the timeout proposed in this policy takes place during a time of high risk in implanting an organ or vessel. The timeout should be designed in a way in which the entire surgical team is on high alert at the time of the double check. All staff involved would need to stop briefly to consider whether there was a risk associated with the use of the vessel and if its use was appropriate at that time. This approach will make people stop and think about what the risks are and pay more attention to the double check process.

Based on the Committee's discussion and review of public comments the following modifications were recommended to the proposal:

- Allow for storage of Hepatitis C antibody positive and Hepatitis B surface antigen positive extra vessels for use in the intended recipient only
- Hepatitis C antibody positive and Hepatitis B surface antigen positive extra vessels must be labeled with the name of the intended recipient for whom the vessel can be used. Further

clarify language to include all serologies on the labels as is consistent with current policy
5.4.3

- Hepatitis C antibody positive and Hepatitis B surface antigen positive vessels can be stored up to 14 days after recovery as is consistent with current policy requirements. The committee agreed that changing the timeframe of storage for this particular subset of vessels may only create more confusion regarding storage requirements and lead to additional errors
- The language proposed in policy 5.10.1 regarding the time out verification for compatibility should be applied to all vessel transplants that take place, not just for the intended recipient

The Committee voted to amend the proposed language described above (**Exhibit A**) as noted above and recommend the revised proposal to the Board for approval in June 2011: 12 For, 0 Opposed, and 0 Abstentions.

****RESOLVED, that Policy 5.10.1 (Vessel Recovery and Transplant) and Policy 5.10.2 (Vessel Storage) shall be modified as set forth below, effective pending notice to the membership:**

5.10.1 Vessel recovery and transplant

- **The consent forms used by the recovering OPO must include language that indicates that vessels will be used for transplant.**
- **The vessels cannot be used other than for the implantation or modification of a solid organ transplant.**
- **Vessels can be shared among transplant ~~programs~~ centers. If sharing occurs between transplant programs, the implanting program must submit to the OPTN a detailed explanation justifying the sharing. The justification will be reviewed by the Membership and Professional Standards Committee (MPSC). The implanting transplant program must notify the OPTN of subsequent disposition of the vessel(s).**
- **If the transplant center stores vessels and subsequently uses the vessels for the intended recipient or another transplant recipient, the OPTN must be notified.**
- **~~If vascular conduits from donors with positive serology for hepatitis are subsequently used in other than the intended recipient, the implanting transplant center must provide a detailed explanation to the OPTN for the use of this conduit. The explanation will be reviewed by the MPSC.~~**
- **The transplant center must verify the ABO, all serology results, container contents, date of expiration, and the UNOS Donor ID of the vessel with the ABO and all serology results of the ~~intended~~ recipient prior to implantation. The documentation of this verification must be maintained within the recipient medical record and made available to the OPTN contractor upon request.**

5.10.2 Vessel storage

The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPTN of outcome and/or use of vessels. This designated person must maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (e.g. subsequent positive serology testing, monitor inventory of

stored vascular conduits). This person must monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessels when expired, and notify the OPTN of its use or disposal.

- ~~Hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels may not be stored for subsequent use.~~
- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- Hepatitis C antibody positive and hepatitis B surface antigen positive vessels may be stored for subsequent use only in the intended recipient.
- The vessels must be stored in a rigid, sterile sealed container labeled with the recovery date, ABO, all serology results, container contents, and the UNOS Donor ID for tracking. The appropriate packaging of vessels should be completed in the ~~donor~~ operating room. Label should clearly state for use in organ transplantation only. Hepatitis C antibody positive and hepatitis B surface antigen positive vessels are also required to be labeled with the name of the intended recipient.
- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.
- The transplant surgeon must have around the clock access to the donor information prior to using the donor vessel(s) in a recipient other than the intended recipient.

2. **ABO Subtyping Policy Proposal** – UNOS staff reviewed with the committee updated data on ABO subtype compatible transplants that were initially reviewed by the ABO subtyping work group at their meeting in January 2011 (**Exhibit B**). After review of the data, a member of the work group presented the Committee with recommendations for changes to current policy language related to subtyping of deceased and living donors that are blood type A or AB as is currently out for public comment.

The Committee reviewed a draft guidance document developed by the work group. The document addresses current issues related to subtyping practices, terminology and reporting by laboratories, and answers questions frequently asked by the transplant community (**Exhibit C**). The work group proposed that this document should be finalized after reviewing comments from select OPOs. It is planned that the document would go to the Board for approval in June prior to the Board's consideration of changes to OPTN policies requiring subtyping. The guidance document is being made available prior to the approved policy changes in an effort to decrease confusion in the community related to terminology and practice. work group believes that the document will encourage increase safety in allocating subtyped organs, when appropriate. The Committee discussed the content of the document and agreed that it would be beneficial for the community to have this type of guidance before proposed policy changes go to the Board for approval in November. The document will need to be updated if policy changes are approved later this year.

After careful review, the Committee voted to recommend the guidance document for consideration by the Board of Directors:

****RESOLVED, that the guidance document “Guidance for ABO Subtyping Organ Donors For Blood Groups A1 and A2” developed by the Operations and Safety Committee be hereby approved, effective June 29, 2011.**

Committee vote: *18 in favor, 0 opposed, and 0 abstentions.*

The committee also discussed the need for field name clarifications and changes to UNetSM, as the system uses some inaccurate terminology related to donors that are non-A₁ or negative for A₁ subtype.

3. **Patient Safety Planning Development (PSPD) Subcommittee** - The Committee reviewed how safety events are reported to the OPTN and the portals by which reporting takes place. The Chair discussed with the Committee the proposal that was presented to the Membership and Professional Standards Committee (MPSC) in October 2010 and the OPTN/UNOS Board of Directors in November 2010 that presented a concept of how all safety related information reported to the OPTN could be integrated into a centralized database to allow real-time analysis of trends and patterns. Integration of the data would assist with real-time analysis and allow the PSPD subcommittee to begin to collect solutions to address issues identified that may be systems gaps. These data could be aggregated and shared with the community with solutions for preventing future occurrences. It was discussed that the subcommittee would not endorse solutions provided, but would help develop a process to make these solutions available for members via a searchable repository.

Members of the PSPD subcommittee reviewed with the Committee a newsletter developed to assist members with understanding the importance of reporting safety events, increase awareness of safety in every day practices, and provide best practices. It is planned that the newsletter would be released in late April 2011. The Committee agreed that the newsletter contain meaningful content and voted 18 for, 0 against, 0 abstentions to make this resource available. Members discussed that the newsletter should be provided via UNOS's monthly communication and archived to track usage by members. The PSPD discussed information included in the first edition would focus on understanding types of safety events that are required to be reported to the OPTN, those that are voluntary for reporting, and what UNOS does with the information once the event is reported. A quick reference guide included in the first edition will outline who should report, when reporting should take place, and who at UNOS to contact to report events (**Exhibit D**). The PSPD subcommittee believes that it is important for members to understand how safety related information, reported to the OPTN, is reviewed by the MPSC and ultimately used to develop education or policy requirements that will enhance the safety of the system and the patients it serves. A section on effective practices will be featured in each newsletter in an effort to share with the community practices that centers have adopted that have proven successful in overcoming systems issues within their own institutions. It was discussed that the second newsletter will focus on how to identify process or systems issues in daily activities, when and how to conduct a root cause analysis (RCA), provide tools and resources to assist with RCA and action plan development, and continue to highlight best practices that could prevent future occurrence of safety events.

The Committee reviewed proposed changes to the Improving Patient Safety electronic reporting system in UNetSM as developed by the PSPD subcommittee. The proposal would add fields to the electronic reporting system that would provide essential data needed for analysis of safety events. The Committee agreed that this proposal was a good path forward to collect essential data but cautioned that the addition of fields to the system could be construed as additional data entry and “too burdensome” for members. The proposed changes should enhance reporting mechanisms and not hinder reporting. The Committee asked UNOS staff to review the fields that were proposed for

addition to the system to assess whether data could be collected elsewhere within the UNOS database and thus additional fields would not be needed.

4. **Patient Safety Reports Trends and Patterns** – Data was reviewed with the Committee on trends and patterns in safety events reported to the OPTN through the electronic reporting system and other portals during the timeframe of September 2009 – September 2010 (**Exhibit E**). This data did not include disease transmission events or living donor adverse events. Data trends continue to show continued reporting of packaging and labeling errors as well as communication issues, such as data entry errors or documentation mishaps, as the top areas in which safety events occur in the field. It was discussed by the committee that there is a significant problem of under-reporting of safety events and it is believed to be due to how the OPTN investigates and reviews these through the MPSC. Members have commented that the process is often punitive in nature and does not promote quality improvement. Those have also commented that there is a “regulatory” feel and component to safety reporting within the OPTN thus making it difficult to encourage safety event reporting that could assist with understanding the systems issues and policy gaps that need correction. The Committee discussed that heightened awareness of safety will not help the system if members do not feel “safe” in reporting safety events. Safety issues are occurring around each person in this field each day but processes are being created to ignore or go around the safety concerns. By creating a feeling of “safety” in reporting, system issues are identified, the system can be made safer, and tools can be provided to the community that allows them to proactively address these issues before an adverse event takes place.

The Committee also reviewed data provided by the Organ Center (OC) that highlighted failures and near misses in transportation related to kidneys allocated through the OC (**Exhibit F**). The Committee discussed that the data did not clearly reflect the number of issues occurring nationwide with all organ allocations, but highlights a need to learn more about circumstances associated with transportation failures and near misses. The Committee discussed that this is especially important with the increase in kidney paired exchanges that are taking place. A member noted that the Kidney Transplantation and Living Donor committees are actively reviewing these types of data and considering whether requirements should be recommended for transportation of paired exchanges and other living donor organs that are transported.

5. **Effective Screening Update** - The Committee reviewed a presentation from the Effective Screening Work Group (ESWG) on a training webinar that took place in September 2010. As part of this educational initiative, letters with data were also provided to select kidney programs that appeared to be outliers in the data for acceptance of expanded criteria kidneys (ECD) when compare with the centers’ donor and candidate selection criteria entered into UNetSM. The results of the surveys performed was reviewed with the committee (**Exhibit G**). The committee commented that the survey results appeared to indicate that centers would like to receive more data on their acceptance practices and are interested in continued education on how to refine selection criteria to effectively screen donors for their candidates.
6. **ABO Verification Process Performed at Donor Hospitals Standardize ABO Verification Form** – The Committee discussed the process of ABO verification at the time of recovering donor organs and at the time of implant of the organs. Members believed that there would be merit to developing a standardized template for documentation of both verification processes and to make it available to the community. Members discussed the need for a crosswalk to be developed noting OPTN, CMS, and Joint Commission policies on ABO verification. This would assist with preparing a best practice verification document that could be used universally. It was agreed that a work group should be created to address this issue.

7. **Public Comment Review** – The Committee considered current proposed policies, which were included in the Public Comment document dated March 11, 2011. The Operations and Safety Committee’s opinion is shown below for the selected proposals the Committee considered within its purview:
- **Proposal to Improve Reporting of Living Donor Status (Living Donor Committee)** – The Committee offered the following comments:
 - The Committee recognizes that it is often difficult for living donor centers to follow their donors greater than 90 days post transplant whether due to financial concerns regarding reimbursement or difficulty in contacting donors that are out of state. There was much discussion of the different challenges to obtaining follow up information on donors, such as: contacting the referring physician, staying in touch with donors via social media or the recipient of the organ, and scheduling follow up appointments for the donor at the recovering center prior to the time follow up data is due. The Committee agrees with the Living Donor Committee that this is necessary to follow up living donors post operatively just as hospitals would follow other surgical patients after surgery to ensure the safety of donors and a good surgical outcome. The Committee voted: 15 For, 1 Against, 1 Abstention.
 - **Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials (Living Donor Committee)** - The Committee offered the following comments:
 - The Committee agreed that packaging, labeling, and shipping requirements should be consistent with living and deceased donors where possible. Consistency will promote less chance for error. The committee does suggest that transplant centers contact their local OPO to get education and share best practices on packaging and labeling processes. The committee voted: 17 for, 0 against, 0 Abstentions.
 - **Proposal to Standardize Label Requirements for Vessel Storage and Vessel Transport (Organ Procurement Organization (OPO) Committee)** - The Committee offered the following comments:
 - The Committee did not agree with this proposal as organs and vessels should be packaged and labeled in the same manner to maintain consistency in process and promote less chance for errors due to transcription or identification. The Committee suggests that vessels should be labeled on the internal and external container as required for solid organs. To remove the OPO requirement for labeling the rigid container could create a situation in which a vessel is removed from the outer barriers and taken into an operating room without a label identifying the donor, serologies, and ABO. If this happens, the time out process for verification of compatibility would be more difficult for transplant centers. OPOs are currently labeling the internal rigid container of vessels that are sent with organs and the Committee agrees that the outside container should also be labeled. OPOs are more of an expert in packaging and labeling then transplant centers as they perform this practice on a daily basis. OPOs and local transplant centers should work together to share best practices in packaging and labeling for safety and consistency. The OSC voted: 0 for, 17 against, 0 Abstentions.
8. **Discussion of Policy 6.0 - Transplantation of Non-resident Aliens** – The Ad Hoc International Relations Committee (AHIRC) requested the OSC for feedback related to their efforts to revise Policy 6.0. The Committee was specifically asked to comment on whether the policy is current with practice, if it could be measured as written, if there were concepts within the policy that should be

eliminated, and to provide any other comments related to the content. The committee discussed policy 6.0 and provided the following comments:

- Transplant centers that transplant donor organs from Bermuda or Bahamas should be not included in the 5% rule when they transplant recipients from Bermuda or Bahamas. Many deceased donors in specific geographic locations are non-resident of resident aliens from these areas.
 - Consider that the 5% rule could apply to the whole transplant center rather than each individual transplant program, as only one transplant of a non-resident alien may put many small programs over the 5% rule. With pediatrics, the 5% rule for each program can be a big problem. The scarcity/demand for the organ is different in every area. Centers could use up their 5% limit transplanting a liver that may be highly scarce in their area versus short waiting lists for other organs, vice versa. This disparity will create imbalance in utilization. Consideration of each program's use of these organs is reasonable, but audits should also look at how many non-resident aliens the center transplants within all their programs. The audit should look at the center as a whole.
 - Recipients that have residence in areas such as Bermuda and Bahamas, but temporarily reside in areas in which organs from donors of Bermuda or the Bahamas are allocated should be given the benefit of transplantation from those donors. They should not be penalized for receiving the organs when their population is donating to the same pool. The number of transplanted recipients from those designated areas is less than the number of organs donated from donors of the area.
 - Identify where the recipients are coming from with audits. Identify if they are from an area with access to transplant but chose to come to the US to be "higher" on the list (or their odds are better in the US) or their area does not have access to transplantation. Also consider whether those getting transplanted for contributing to society (for example they have a home here, work here, pay taxes, etc.) as we cannot tell these folks that they cannot have access to healthcare just because they want to pay cash.
 - Candidates that are in the country illegally may not give the transplant center accurate information and could have an inappropriate identification to prove legal status. Thus, documentation of legal status should not be the only consideration with these audits.
 - Non-resident aliens may have a green card in process when they get transplanted as a non-resident alien. Consider if the 5% threshold has already been met, but the foreign national waiting on green card approval has an acute medical situation making them priority for an organ transplant, they may not get transplanted if the center is afraid there will be repercussions for being over the 5% threshold.
9. **Next 2011 Meeting Date** – The full Committee will meet again on September 15, 2011 at O'Hare Hilton Hotel, Chicago, Illinois.

OPTN/UNOS OPERATIONS COMMITTEE MEETING ATTENDANCE

Name	Position	Chicago, Illinois April 7, 2011
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	
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	
J.T. Rhodes, CPA	At Large Representative	
Michael Ison, MD	At Large Representative	Part in person, part by phone
Anton Skaro, MD, PhD	At Large Representative	x
Sharon E. Swofford, MA, RN, CNN, CCTC	At Large Representative	x
Janel N. Tedesco, ACNP, CCTC	At Large Representative	x
Donna Woods, EdM, PhD	At Large Representative	x
Michael Hagan, DO, MHSA, CMQ	Visiting BOD Member	x
Raja Kandaswamy, M.D.	SRTR	x
Robert W. Walsh	Ex Officio/HRSA	By Phone

UNOS staff attending:

Lin McGaw, RN, MEd, Director Professional Services Department
 Darren Stewart, Biostatistician, UNOS Research Department
 Kimberly Taylor, RN, Patient Safety Specialist, Committee Liaison

UNOS staff attending by phone:

Jory Parker, Business Analyst, UNOS