At-a-Glance

- **Proposal to Require Extra Vessel(s) Disposition to be Reported to the OPTN within Five Days of Transplant or Disposal**

- **Affected Policy:** Policy 5.10.2 Vessel Storage

- **Operations and Safety Committee**

  The Operations and Safety Committee is proposing policy language within section 5.10.2 (Vessel Storage) to require transplant centers to report the disposition of extra vessels to the OPTN within five days of transplant or disposal. This proposal will enhance patient safety and recipient outcomes in cases where extra vessels are transplanted by providing timely information on the disposition of extra vessels that could be part of an investigation by the OPTN/UNOS *ad hoc* Disease Transmission Advisory Committee's (DTAC) review of a potential disease transmission event. It is expected that this proposal can reduce the risk of disease transmission when the donor of the extra vessel is potentially at risk for transmitting disease a primary or secondary recipient.

- **Affected Groups**
  Lab Directors/Supervisors
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Number of Potential Candidates Affected**
  This proposal could affect any potential transplant recipient who could receive an extra vessel during the time of transplant or for vascular revisions post transplant.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposal addresses the OPTN/UNOS Strategic Goal to promote safe, high quality care for transplant recipients. This proposal also meets provisions of the Final Rule as outlined in §121.4.

- **Specific Requests for Comment**
  OPTN Policy currently requires transplant centers to report the final disposition of extra vessels to the OPTN, but obtaining this information has been problematic as policy does not outline a required timeline for reporting. The Committee is requesting specific feedback on a proposed requirement for reporting extra vessel final disposition within five days. Please read the entire document for background and history on the issue and comment on the appropriateness of the time specified for reporting.

Proposal to Require Extra Vessel(s) Disposition to be Reported to the OPTN within Five Days of Transplant or Disposal

Affected Policy: Policy 5.10.2 Vessel Storage

Operations and Safety Committee

Summary and Goals of the Proposal:

The Operations and Safety Committee is proposing policy language within section 5.10.2 (Vessel Storage) to require transplant centers to report the disposition of extra vessels to the OPTN within five days of transplant or disposal. This proposal will enhance patient safety and recipient outcomes in cases where extra vessels are transplanted by providing timely information on the disposition of extra vessels that could be part of an investigation by the OPTN/UNOS *ad hoc* Disease Transmission Advisory Committee's (DTAC) review of a potential disease transmission event. It is expected that this proposal can reduce the risk of disease transmission when the donor of the extra vessel is potentially at risk for transmitting disease a primary or secondary recipient.

Background and Significance of the Proposal:

Transmission of infectious disease through organ transplant is a patient safety issue and often can be of public health significance. Disease transmission via the use of deceased or living donor organs and extra vessels can result in serious illness or death in recipients. Therefore, it is important that the OPTN have complete and timely information on the use of extra vessels when cases of potential disease transmission are reported.

In June 2004, the Centers for Disease Control and Prevention (CDC) confirmed a diagnosis of rabies in three organ recipients of transplanted organs and from their common donor. An iliac artery was recovered from the common donor and the extra vessel was stored for future use. Prior to the identification of rabies disease in the donor, the extra vessel was transplanted into another recipient during a liver transplant. The patient subsequently expired.[1] In July 2004, the OPTN began the process of developing a system for members to report potential disease transmissions, and a subcommittee was formed to further address issues raised with extra vessel recovery, storage, and transplant. Proposed policies regarding extra vessel monitoring, tracking, and reporting were subsequently passed by the OPTN/UNOS Board of Directors.

In September 2009, a donor-derived transmission of hepatitis C was identified during review of a potential disease transmission case by DTAC. The transmission occurred after a stored hepatitis C antibody positive deceased donor extra vessel was transplanted into a living donor liver recipient that was hepatitis C negative prior to transplant. The investigation of this case identified that the extra vessel was appropriately labeled as being hepatitis C positive, but was not recognized by the surgical team prior to the time of transplant. In response to this event, the Operations and Safety Committee

[1] Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report (MMWR)– Update: Investigation of Rabies Infections in Organ Donor and Transplant Recipients --- Alabama, Arkansas, Oklahoma, and Texas, 2004, July 16, 2004 / 53(27);615-616.

(OSC) was directed to assemble a work group to evaluate current OPTN policy and address questions raised regarding the need for additional oversight extra vessel(s) during recovery, storage, and transplant.

Review of OPTN data on extra vessel disposition reporting highlighted problems with members' compliance in reporting extra vessel final disposition. UNOS Data Quality staff also indicated that some transplant centers report monthly disposition, but many are sporadic in reporting and may not provide information on the use of extra vessel until the time of a site survey, which may include three years of data. The OSC recognized that the two disease transmission events were rare instances, but there has been a steady increase in the number of potential disease transmission events reported to the OPTN since the June 2004 rabies transmission was identified. Delayed reporting of extra vessel disposition could also add to the problem of under-recognition of disease transmission via the use of extra vessels and could hinder investigations that could protect the health and well being of transplant recipients.

The OSC formed an ad hoc work group to include other OPTN committee representatives and others with experience in the recovery, storage, tracking, and transplant of extra vessels. During the review of current policy in place, the work group requested additional data that would identify the number of transplant recipients that have the received extra vessels during the original transplant procedure and the number of secondary recipients that have received extra vessels for reconstruction or re-vascularization after the original transplant. Although the policy requires transplant centers to report final extra vessel disposition to the OPTN, the data revealed the areas of deficiency that the UNOS Data Quality staff had previously communicated.

- ***Collaboration:*** The OSC was directed to assemble a work group to evaluate current OPTN policy and address questions raised regarding the need for additional oversight of extra vessels during recovery, storage, and transplant. A work group of multiple OPTN committees was assembled to include ad hoc members with expertise in vessel recovery, handling, storage, tracking, and disposition reporting. OPTN committees represented on this work group were as follows: Membership and Professional Standards Committee (MPSC), Transplant Administrators Committee (TAC), Transplant Coordinators Committee (TCC), OSC, Organ Procurement Organization Committee (OPO), as well as UNOS Data Quality staff.

- ***Alternatives considered:*** The OSC considered that providing education to the transplant community regarding the extra vessel disposition reporting may alleviate the issues outlined within this document. It was ultimately determined that current policy did not define a timeline for reporting extra vessel disposition and that issue would need to be corrected prior to education on this topic. Otherwise, the OPTN would not have policy in place to monitor compliance with reporting extra vessel disposition. The OSC also considered applying a reporting timeline to vessel usage only (during the transplant or modification procedure) and not to vessel discard. However, the committee decided that vessel data reporting should be similar to that of organs, for which the reporting of final disposition (transplant or discard) is required.

- ***Strengths and weaknesses:*** The proposed reporting would provide important information regarding the disposition of extra vessels to the OPTN when reported potential disease transmission events are reviewed by DTAC and/or the CDC. In these events, it is important to identify all recipients of organs or extra vessels to allow transplant center personnel to make treatment decisions when an infectious disease may have been transmitted. If this proposal is

approved, transplant centers must develop a process or procedure by which extra vessel disposition information is reported to the OPTN within 5 days of use or disposal.

- ***Description of intended and unintended consequences**:* This proposal will enhance patient safety and recipient outcomes when extra vessels are used in a transplant, transplant reconstruction, or other transplant related vascular revisions of the organ recipient. It is intended to prevent recipients from contracting donor-transmitted infections by requiring more complete and timely disposition reporting to the OPTN. This information is critically needed for prompt notification of transplant centers receiving organs and vessels and for appropriate treatment of patients.

Supporting Evidence and/or Modeling:

Currently, extra vessel data collection by the OPTN differs from that for solid organs due to the difference in timing, storage, and usage of extra vessels for transplant or post transplant procedures. For each organ, organ procurement organizations (OPO) must indicate in DonorNet® (Donor Organ Disposition) when extra vessels are sent with an organ. When extra vessels are used for the original transplant, programs can enter the extra vessels' donor identification (ID) at the time of waiting list removal to report the transplant of the vessel. Programs may also report extra vessel use after waiting list removal via the "Vessel Use Report" in Waitlist℠. Alternatively, vessel disposition can be reported via fax or email of the "Vessel Transplantation/Destruction form" attached to the OPTN Evaluation Plan.[2] UNOS Data Quality staff indicate that members report the following information via this route:

- Extra vessels used during the original transplant procedure in the intended recipient when not reported through Waitlist℠;
- Extra vessels that are stored and subsequently used in the intended recipient after the time of the original transplant procedure (e.g. for vascular reconstruction or revision);
- Extra vessels that are stored and used during the original transplant procedure of a secondary recipient;
- Extra vessels that are stored and later used in a secondary recipient after the transplant procedure (e.g. for vascular reconstruction or revision); and
- Extra vessels not used for transplant and are disposed of.

To assess the level of member compliance with OPTN vessel disposition reporting requirements, the Operations and Safety Committee asked to review data showing the number of donors from which extra vessels were recovered, and the number with disposition reported, including reported vessel usage at the time of waitlist removal. The data was to evaluate completeness of vessel disposition reporting overall and by transplant program.

[2] OPTN Evaluation Plan link http://optn.transplant.hrsa.gov/content/policiesAndBylaws/evaluation_plan.asp

Table 1. Cases Where Vessels Reported Recovered and Sent with Deceased Donor Kidney, Liver, Pancreas, or Intestine During 2008 – 2010

	2008-2010 Reported Outcome of Vessels									
	Transplanted Into Same Recipient		Transplanted Into Another Recipient		Reported Destroyed		Status Not Yet Reported		Totals	
Era	N	%	N	%	N	%	N	%	N	%
2008-2009	1,718	12.1	218	1.5	5,142	36.3	7,077	**50.0**	14,155	100.00
2010	790	11.5	114	1.7	2,139	31.1	3,840	**55.8**	6,883	100.00
Total	2,508	11.9	332	1.6	7,281	34.6	10,917	**51.9**	21,038	100.00

Table 1 shows that more than 21,000 kidney, liver, pancreas, and intestine deceased donors had vessels recovered and sent during the years 2008 through 2010. More than 10,000 (51.9%) of the vessels do **not** have a status reported to the OPTN. The percentage of vessels that do not have a status reported to the OPTN increased from 50.0% during the years 2008-2009 to 55.8% in 2010.

Table 2. Transplants from 1/2011 – 11/2011 Vessel Usage Reported at Waitlist Removal or by Fax

	WERE EXTRA VESSELS USED IN THE TRANSPLANT PROCEDURE:						Total (ALL)
	Unknown		No		Yes		
	N	%	N	%	N	%	N
Transplanted organ							
Thoracic	427	11.1	3,413	88.5	17	0.4	**3,857**
Intestine	5	4.0	44	35.5	75	60.5	**124**
Kidney	1,630	10.6	13,709	88.9	74	0.5	**15,413**
Pancreas/KP	170	16.9	410	40.7	428	42.5	**1,008**
Liver	872	14.9	4,547	77.9	421	7.2	**5,840**
Total (ALL)	**3,104**	**11.8**	**22,123**	**84.3**	**1,015**	**3.9**	**26,242**

Table 2 shows data from January 2011 to the end of November 2011 indicating that more than 1,000 transplants were reported as having used extra vessels during this timeframe. For 3,104 transplant recipients, however, extra vessels disposition was reported as "unknown." Kidney recipients account for most transplants where vessel use is not reported; but of extra vessel use that is "known," very few kidney transplants (0.5%) required extra vessels.

The data in the tables above shows that over 10,000 extra vessels recovered during the years of 2008-2010 have unreported disposition to the OPTN. In the most recent year of 2011, over 3,000 transplant recipients were removed from the waitlist with "were extra vessels used during the transplant procedure?" answered as "unknown."

Expected Impact on Living Donors or Living Donation:

This proposal does not impact living donors but will enhance the safety of living donor recipients requiring the use of an extra vessels for completion of the transplant procedure or post transplant procedures.

Expected Impact on Specific Patient Populations:

This proposal will enhance patient safety for all organ and extra vessel transplant recipients, as more than 1000 recipients were reported to have required the use of extra vessels from January - November of 2011 (Table 2).

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal will result in improved patient safety and recipient outcomes for those receiving extra vessels at the time of an organ transplant or reconstruction or revascularization procedure. The proposal addresses the HHS Program Goal of patient safety and addresses the OPTN/UNOS Strategic Plan Goal to promote transplant patient safety and improve post transplant survival when disease transmission may be transmitted via the use of an extra vessel.

The OSC's goals for these policy modifications meet provisions of the Final Rule as outlined in §121.4[3].

Plan for Evaluating the Proposal:

The OSC will monitor reports of compliance provided by the UNOS Department of Evaluation and Quality (DEQ) and Research staff:

- The OSC will request data to assess the number of extra vessels recovered for transplant, those reported as transplanted or disposed, and extra vessels usage reported at the time of waitlist removal or via fax/email to the UNOS Data Quality Department.
- The OSC will inquire of DTAC and/or DEQ to assess whether extra vessel disposition information is being made available to the OPTN as required by policy and whether the information provided is timely and sufficient for investigation into cases of potential disease transmissions and for site survey analysis;
- The OSC will request the above information for review twice a year to assess the appropriateness of the policy.

Additional Data Collection:

This proposal does not require additional data submission through UNet℠.

[3] 42 CFR Part 121, see http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp

Expected Implementation Plan:

If approved by the Board at their November 2011 meeting, this policy will go into effect on February 1, 2012. To implement the proposed policy modifications, the transplant center must develop, implement, and comply with a procedure for reporting disposition of extra vessels transplanted or disposed of within five days of the event.

The proposed policy will not require programming in UNet℠.

Communication and Education Plan:

If approved by the Board of Directors, the transplant community will receive information regarding approved policy language and implementation date via a Policy Notice. The Operations and Safety Committee will provide additional information about the changes in the UNOS monthly electronic newsletter and will address questions that may arise during a training webinar.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice [This notice informs community that policy modifications were approved by the OPTN/UNOS Board of Directors.]	Lab Directors/Supervisors; Transplant Administrators; Transplant Data Coordinators; Transplant Physicians/Surgeons; Transplant Program Directors; Organ Recipients; Organ Candidates; Living Donors; Donor Family Members; General Public.	Electronic – Included in the monthly e-newsletter sent on the 3rd week of each month	30 days after the board approves the change.
Notice to intestine, kidney, liver, pancreas, pediatric programs, and OPOs explaining changes and providing an avenue for questions	Intestine, kidney, liver, pancreas, pediatric programs staff, and OPO Staff	Electronic - Included in the monthly e-newsletter sent on the 3rd week of each month	Within 30 days of Board approval
OPTN Evaluation Plan	OPTN transplant centers, OPO, and histocompatibility laboratories	Electronic – Available on the OPTN website under the policy management tab	Updates to the document are released quarterly
Education/Training Activities			

Education/Training Description	Audience(s)	Deliver Method(s)	Timeframe and Frequency
Educational Webinar	Directors of Organ Procurement, Lab Directors/Supervisors, OPO Executive Directors, OPO Medical Directors, OPO Coordinators, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Data Coordinators	LiveMeeting Teleconference	One time live with archived recording

Compliance Monitoring:

During on-site reviews, DEQ site surveyors currently review each transplant center's extra vessel storage refrigerator for proper storage and required labeling of stored extra vessels, reviews the center's policy and procedure for storage of extra vessels, and reviews the disposition tracking log for documentation of final disposition.

DEQ staff may detect potential violations of this proposed policy during on site reviews by reviewing the vessel log and reporting records to verify that each transplantation or disposal of vessels was reported within 5 days. DEQ staff also reviews a monthly report of any hepatitis positive vessels that are stored and subsequently transplanted.

DEQ staff will investigate any reports of noncompliance. A corrective action plan will be requested if the transplant center does not comply with the requirements of Policy 5.10. All issues of noncompliance and survey results will be prepared for the OPTN/UNOS Membership and Professional Standards Committee (MPSC) to review in a blinded fashion.

Policy Proposal:

Proposed OPTN policy language is underlined (example) and deleted language is struck through (~~example~~).

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~~ extra vessels). This person must monitor the refrigerator,

ensure records are up to date and available with the ~~conduits~~ vessels, destroy the vessels when expired, and ~~notify~~ report the vessel's use or disposal to the OPTN within 5 days of when the Transplant Center uses or disposes of the vessel~~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).
- The vessels must be stored in a rigid, sterile sealed container and must be protected by a triple sterile barrier, one of which must be the rigid container. labeled with the recovery date, ABO, ABO subtype when used for allocation, infectious disease results. container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be affixed to the outer most sterile barrier bag and information on the label must include the recovery date, ABO, all infectious disease results, container contents, and the UNOS Donor ID. If the donor is in a "high risk"[1] group as defined by the US Public Health Service (PHS) guidance[1], the label must indicate that the vessels are from a donor who meets the PHS criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state for use in organ transplantation only. If removed from the triple sterile barrier, the transplant center must re-label the vessels prior to storage.
- 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.

[1]Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994;May 20/ 43(RR-8):1-17. http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm