At-a-Glance

- **Proposal to Prohibit Storage of Hepatitis C Antibody Positive and Hepatitis B Surface Antigen Positive Extra Vessels**

- **Affected Policies:** Policy 5.10.1 Vessel Recovery and Transplant and Policy 5.10.2 Vessel Storage

- **Operations and Safety Committee**

- Under this proposal, the storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels would be prohibited when they are not transplanted into the intended recipient for whom the organ and extra vessel were procured.

- **Affected Groups**
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Organ Recipients
  Living Donors
  Donor Family Members

- **Number of Potential Candidates Affected**
  This proposal could affect any potential transplant recipient on the Waitlist® who could unintentionally receive a hepatitis C antibody positive or hepatitis B surface antigen positive extra vessel.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposal addresses OPTN/UNOS Strategic Goals to promote safe, high quality care for transplant recipients by reducing the risk of disease transmission when extra vessels are transplanted. This proposal also meets provisions of the Final Rule as outlined in §121.6(a).

- **Specific Requests for Comment**
  Please comment on the entire document in addition to the following question:
  - Does the proposal effectively decrease the risk of disease transmission by transplant of stored hepatitis seropositive extra vessel?

Proposal to Prohibit Storage of Hepatitis C Antibody Positive and Hepatitis B Surface Antigen Positive Extra Vessels

Affected Policies: Policy 5.10.1 Vessel Recovery and Transplant and Policy 5.10.2 Vessel Storage

Operations and Safety Committee

Summary and Goals of the Proposal:

The Operations and Safety Committee is proposing additional policy language for OPTN policy 5.10.2 (Vessel Storage) to prohibit the storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels. This proposal also includes modifications to policy 5.10.1 requiring transplant centers to verify the donor extra vessels ABO, all serology results, container contents, date of expiration and the UNOS Donor ID with the ABO and all serology results of the intended recipient prior to implantation. Extra vessels are defined as vessels taken during the organ procurement process with the intent to be used as a vascular conduit. Anything directly attached to the organ (without surgical modification) to be transplanted is not considered an extra vessel.

The proposed language and modifications will enhance patient safety and recipient outcomes related to the storage and transplant of extra vessels. It is expected that this proposal will reduce the risk of disease transmission from transplant of extra vessels into secondary recipients when the vessels are not transplanted into the recipient for whom the donor organ was originally procured.

Background and Significance of the Proposal:

In September 2009, a donor-derived transmission of hepatitis C was identified during review of a potential disease transmission case by the OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee (DTAC). The transmission occurred after a stored hepatitis C antibody positive deceased donor extra vessel was inadvertently transplanted into a living donor liver recipient that was hepatitis C negative. It was identified that the extra vessel was appropriately labeled per OPTN policy, but the transplant center **did not** recognize that the label indicated the extra vessel to be hepatitis C antibody positive at the time of transplant. In response to this event, the Operations and Safety Committee were directed to assemble a work group with representatives from other OPTN committees to review current policy requirements related to vessel recovery, storage, and transplant. The vessel policy work group was created and consisted of subject matter experts understanding current practices in the procurement and transplant of extra vessels. Also included within the composition of this group was an infectious disease physician, CDC representatives, a transplant administrator, and an organ procurement representative. Once the work group was created it focused on identifying how to decrease the risk of hepatitis transmission when an extra vessel is transplanted into a secondary recipient. Policy modifications were recommended by the work group to the Operations and Safety Committee that would improve patient safety and recipient outcomes.

During the vessel policy work group's review of the hepatitis transmission event, several areas of concern for patient safety were highlighted:

- Current OPTN policy allows for storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels that are not transplanted into the intended recipient for which the donor organ and extra vessel were procured;

- There are no requirements to verify extra vessel information such as ABO, serology results, container contents, date of expiration, and UNOS Donor ID with the intended recipient's ABO and serology information to assess for compatibility prior to the time of transplant; and

- Hepatitis positive extra vessels are often stored within the same refrigerated system as other hepatitis negative extra vessels and tissues making it easy to obtain vessels that may not be compatible for the secondary recipient's situation.

As a result of the patient safety issues highlighted above, the Operations and Safety Committee agreed with recommendations from the vessel policy work group to prohibit storage of extra vessels that are positive for hepatitis C antibody and hepatitis B surface antigen to reduce the risk of disease transmission when transplanting a stored extra vessel.

The work group also considered eliminating storage of hepatitis B core antibody positive extra vessels, but determined that these types of vessels do not involve a higher concern for disease transmission. Studies have shown that some organs, other than the liver, procured from hepatitis B core antibody positive donors have been safely transplanted into recipients with minimal risk for transmitting hepatitis B[1],[2]. Livers that are hepatitis B core antibody positive 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[3],[4].

In the review of extra vessel procurement practices and other issues related to disposition reporting, the vessel policy work group became aware that many within the transplant community may not have appropriate knowledge regarding the definition of an extra vessel, leading to errors in reporting disposition and documenting their use. To increase awareness and understanding of the term "extra vessel" the following definition was developed by the work group and approved by the Operations and Safety Committee:

> Extra vessels are those vessels taken during the organ procurement process of deceased or living donors with the intent to use them as a vascular conduit*. Anything directly attached to the organ (without surgical modification) to be transplanted is **not** considered an extra vessel.

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[1] Madayag RM, Johnson LB, Bartlett ST, Schweitzer EJ, Constantine NT, McCarter Jr, RJ, Kuo PC, Keay S, Oldach,DW. "Use of Renal Allografts from Donors Positive for Hepatitis B core Antibody Confers Minimal Risk for Subsequent Development of Clinical Hepatitis B Virus Disease." *Transplantation.* 1997, December 27; 64 (12): 1781-6.

[2] Fabrizio, F, Bunnapradist S, Martin P. "Transplanting kidneys from donor with prior hepatitis B infection: one response to the organ shortage." *Journal of Nephrology.* 2002, November-December; 15(6)L 605-13.

[3] Wachs ME, Amend WJ, Ascher NL, Bretan PN, Emond J, Lake JR, Melzer JS, Roberts JP, Tomlanovich SJ, Vincenti F, et al. "The Risk of Transmission of Hepatitis B from HBsAg (-), HBcAb (+), HBIgM (-) Organ Donors."*Transplantation.* 1995, January 27; 59 (2): 230-4.

[4] Cholongitas, Evangelos, Papatheodoridis, George V., Burroughs, Andrew K. "Liver grafts from anti-hepatitis B core positive donors: Asystematic review." *Journal of Hepatology.* 2010; vol. 52: 272-279.

*Vascular conduits are routinely taken from areas not immediately connected to the transplantable organ (i.e. iliac artery or vein, carotid artery or jugular vein, etc.) and are necessary to reconstruct vasculature of a transplanted organ.

Collaboration

The vessel policy work group is made up of representatives from the OPTN/UNOS Membership and Professional Standards Committee (MPSC), Pediatric Transplantation Committee, DTAC, Transplant Administrators Committee (TAC), Liver and Intestinal Organ Transplantation Committee, and the Centers for Disease Control and Prevention (CDC). The work group consulted with TAC on the policy proposal to ensure that issues related to transplant center procedures and administration were appropriately considered in the proposal. The TAC supported the proposal.

Alternatives considered

The vessel policy work group discussed alternatives to storage and transplant of hepatitis positive extra vessels in secondary recipients and the impact of prohibiting their storage. Liver, kidney, and pancreas transplant surgeon representatives on the work 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 or allograft conduits have higher rates of thrombosis. The surgeons also agreed 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. The vessel policy work group members 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%, with a conservative upper estimate of 10%.

Safeguards are necessary to prevent transmission of disease, but the practice of storing extra vessels cannot be ruled out altogether. Extra vessels can be life saving during transplant and reconstruction of vasculature after transplant as referenced in the America Society of Transplant Surgeons (ASTS) position statement on live vascular grafts (**Exhibit A located on the OPTN Public Comment Website**). Transplant surgeons on the vessel policy work group indicated that there are instances in which surgeons may not be aware of the need for an extra vessel to complete the transplant surgery or reconstruction of vasculature, so it is important that extra vessels be stored and available for these cases.

Strengths and weaknesses

This proposal will decrease the risk of disease transmission by prohibiting storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels. The potential impact on extra vessel availability for patients receiving organ transplants from donors that are hepatitis C antibody positive and hepatitis B surface antigen positive (e.g., hepatitis C antibody positive recipient receiving a hepatitis C antibody positive liver) was considered as part of this proposal. 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%, with a conservative upper estimate of 10%. Based on the conservative estimate of 10%, along with an analysis of the supply and demand for extra vessels across donation service areas (DSA), shortages are anticipated to occur but only rarely, as described in more detail later in the document.

Intended and unintended consequences

This proposal will decrease the risk of unintended disease transmission by prohibiting storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels, and thus reducing the risk that those types of extra vessels could be used for patient secondary recipient. It is also not intended that these extra vessels should be stored for use in the initial recipient after the time of the original transplant.

The Operations and Safety Committee considered that there could potentially be rare instances in which an extra vessel would not be available for reconstruction of vasculature after the initial transplant for recipients of hepatitis C antibody positive or hepatitis B surface antigen positive organs. In these instances it would be expected that there would be an increase in the number of extra vessels shared among transplant centers or, in emergency situations, use of a synthetic substitute if no donor extra vessels were available.

Supporting Evidence and/or Modeling:

In 2008-2009, OPTN data show a total of 14,171 organs procured for purpose of transplantation with which extra vessels were reported as being sent, as outlined in Table 1 below. Of the extra vessels reported as sent, approximately 12.1% were transplanted into the same recipient who received the organ, 1.5% were reported as being transplanted into a secondary recipient, and approximately 34% were destroyed. Disposition has not been reported for about 52% of sent extra vessels as current OPTN policy does not identify a timeframe for reporting disposition.

Table 1. Reported CDC High Risk, HBV, HCV, and HTLV 1/2 Status in Cases Where Vessels Reported Recovered with Kidney, Liver, Pancreas, or Intestine Deceased Donor Recovery During 2008-2009

	Reported Outcome of Vessels								Total	
	Transplanted Into Same Recipient		Transplanted Into Another Recipient		Reported Destroyed		Status Not Yet Reported			
	N	%	N	%	N	%	N	%	N	%
Year										
2008	851	12.0	115	1.6	2,325	32.7	3,810	53.7	7,101	100.0
2009	862	12.2	97	1.4	2,480	35.1	3,631	51.4	7,070	100.0
Total	1,713	12.1	212	1.5	4,805	33.9	7,441	52.5	14,171	100.0

Table 2, below, includes extra vessels reported as recovered and sent by the OPO along with kidneys, livers, pancreata and intestines, shows that only 2.6% of these extra vessels were from hepatitis C antibody positive donors and 0.1% of extra vessels were from hepatitis B surface antigen positive donors.

Table 2. Reported HBV and HCV Status in Cases Where Vessels Reported Recovered with Kidney, Liver, Pancreas, or Intestine Deceased Donor Recovery During 2008-2009

	Year					
	2008		2009		Total	
	N	%	N	%	N	%
Donor HCV Status:						
Indeterminate	4	0.1	0	0	4	0.0
Negative	6,880	97.3	6,867	97.5	13,747	97.4
Positive	185	2.6	178	2.5	363	2.6
Total	7,069	100.0	7,045	100.0	14,114	100.0
Donor HBV Surface Antigen Status:						
Negative	7,055	99.8	7,029	99.8	14,084	99.8
Not Done	10	0.1	8	0.1	18	0.1
Positive	2	0.0	8	0.1	10	0.1
Unknown	2	0.0	0	0	2	0.0
Total	7,069	100.0	7,045	100.0	14,114	100.0

In 2009 OPTN shows that there were approximately 7070 cases in which extra vessels were procured for the purpose of transplantation, as shown in Table 1. As indicated in Table 2, OPTN data show 178 cases in which extra vessels were procured from a hepatitis C antibody positive donor and eight cases in which extra vessels were procured from a hepatitis B surface antigen positive donor. OPTN data show that a reported 862 intended recipients and 97 secondary recipients required the use of extra vessels, for a total of 959 in 2009. Of these, it is estimated that between 50 and 250 recipients who were hepatitis negative required the use of stored extra vessels [5]. Without prohibition of hepatitis positive vessel storage, each of these 50 to 250 recipients may be at risk of accidentally receiving a hepatitis positive vessel, due to mislabeling the vessel container, misreading or overlooking positive serological results on the label, etc. Under current policy the actual risk of transmission has proven to be very small, in part because only about 2.5% of recovered extra vessels are hepatitis positive as indicated in Table 2. Yet the risk was still high enough to have resulted in a hepatitis transmission event in 2009**.**

A vessel supply and demand analysis was conducted to evaluate the impact of a policy prohibiting the storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels on the availability of extra vessels for recipients of hepatitis seropositive organs. To quantify the likelihood of a potential extra vessel shortage – defined as having no available extra vessels on hand within 14 days of transplanting a hepatitis C antibody positive or hepatitis B surface antigen positive organ, regardless of whether the recipient actually needs the extra vessel – the number of "available" extra vessels sent to each DSA for each two-week period between September 1, 2008 and December 31, 2009 was tabulated.

[5] Of 7,733 liver, pancreas, kidney-pancreas, and intestine transplants in 2009, 2,733 recipients were hepatitis C or hepatitis surface antigen positive, leaving 5,000 recipients potentially at risk for Hepatitis transmission from a vessel should they require one. Of these 5,000 recipients, the Vessels Policy Working Group estimated that only about 1% to 5% (50 to 250) will require stored vessels due to vascular complications.

The same was done for transplants using organs of hepatitis positive donors performed within each DSA (**Exhibit B located on the OPTN Public Comment Website**).

All extra vessels reported as "destroyed" were assumed to have been discarded because the need for their use did not arise within the refrigeration/shelf-life of each extra vessel; this assumption was confirmed as being reasonable by the vessel policy work group. Thus, all hepatitis negative extra vessels reported as "destroyed" were considered as part of the "available" vessel supply that could be used for a hepatitis B or C positive organ recipient if the need were to arise. The extra vessels reported as transplanted were assumed to be unavailable for use in hepatitis B or C positive organ recipients for reconstruction of vasculature post transplant, since, of course, they were used to meet the demand from other recipients.

The supply and demand analysis, as outlined in Table 3 below, indicates that "potential" shortages would not be uncommon under such a policy, with approximately ten DSA's likely to experience such a situation during a one-year period of time. However, while extra vessels are most frequently used during liver, pancreas, or intestine transplant procedures, 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%, with a conservative upper estimate of 10%. By incorporating this 10% estimate into the analysis, the number of DSA's likely to experience an "actual" vessel shortage dropped to approximately one.

Table 3. Vessel Supply & Demand Analysis Results

	Vessel Supply Assumptions			Analysis Results	Vessel Demand Assumption	Analysis Results
Scenario	# Vessels Sent	# Vessels Available	Vessel Sharing	# of DSA's likely to experience a "potential shortage" within 1 year	LI/PA/KP/IN recipient needing stored vessels within 14 days of transplant	# of DSA's likely to experience an "actual shortage" within 1 year
Baseline	As Reported	All Reported Destroyed + 70% of Unknowns	Within DSA	10	0.10	1

Given the uncertainties in the vessel data due to newly identified incomplete reporting of vessel procurement and disposition, several estimates were made to complete the analysis. To evaluate the impact of changes in these assumptions on the results, a sensitivity analysis was performed. Several of the key assumptions were substantially altered, generating six analysis scenarios (including the baseline scenario). Across all of the scenarios, the conclusions changed very little: only one to two DSA's are likely to experience an actual shortage event within a one-year period of time. In summary, the analysis concludes that though shortages may happen, it would be rare.

The Operations and Safety Committee agreed with the vessel policy work group analysis 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.

Expected Impact on Living Donors or Living Donation

This proposal does not impact living donors but could potentially protect living donor recipients requiring extra vessels from a deceased donor to complete the living donor transplant procedure.

Expected Impact on Specific Patient Populations

This proposal affects potential transplant recipients, or candidates, as more than 950 recipients required the use of extra vessels in 2009. Of these, it is estimated that between 50 and 250 recipients who were hepatitis negative required the use of stored extra vessels [6]. Without prohibition of hepatitis positive extra vessel storage, each of these 50 to 250 recipients may be at risk of accidentally receiving a hepatitis positive vessel.

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

It is anticipated that modification to OPTN policy related to vessel recovery, storage and transplant, will result in improved patient safety and recipient outcomes.

The Operation and Safety Committee's proposal addresses the HHS Program Goal of patient safety and addresses the OPTN/UNOS Strategic Plan Goal to promote safe, high quality care for transplant recipients and living donor recipients by reducing the risk of disease transmission when extra vessels are transplanted.

The Committee's goals for these policy modifications meet provisions of the Final Rule as outlined in §121.6(a)[7].

Plan for Evaluating the Proposal:

The Committee will monitor reported safety situations reported to the OPTN's Patient Safety System℠ to assess whether there have been decreases in the availability of extra vessels for transplant into hepatitis seropositive secondary recipients due to prohibited storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels. It will also assess whether reports of potential transmission of hepatitis have been reported for review by DTAC through the use of extra vessels that were not identified as hepatitis seropositive. The Committee will also review OPTN data to access whether any secondary recipients received hepatitis positive extra vessels to ensure adherence to the policy requirements for storage restriction.

The above data will be reviewed twice yearly and as needed by the Committee to assess if additional policy modifications are required to improve patient safety in the area of vessel recovery, storage, and transplantation.

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[6] Of 7,733 liver, pancreas, kidney-pancreas, and intestine transplants in 2009, 2,733 recipients were Hepatitis C or Hepatitis Surface Antigen positive, leaving 5,000 recipients potentially at risk for Hepatitis transmission from a vessel should they require one. Of these 5,000 recipients, the Vessels Policy Working Group estimated that only about 1% to 5% (50 to 250) will require stored vessels due to vascular complications

[7] 42 CFR Part 121, see http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

This policy will become effective 30 days after the transplant community receives notification of the OPTN/UNOS Board of Directors' approval of the proposed policy.

The proposed policy will not require programming in UNet[SM].

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 of the changes and allow for questions that may arise in the UNOS monthly electronic newsletter and the UNOS Update Magazine.

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.]	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 Social Workers, Transplant Data Coordinators	Electronic – Included in the monthly e-newsletter sent on the 3rd Monday 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 Monday 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

Monitoring and Evaluation:

The UNOS Department of Evaluation and Quality (DEQ) site surveyors currently review transplant centers' extra vessel storage refrigerator for proper storage and required labeling of stored extra extra vessels, review the centers' policy and procedure for storage of extra vessels, and the disposition tracking log for documentation of final disposition.

To implement this proposed policy modification the transplant center must:

- Develop, implement and comply with a procedure for discard of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels when they are not used in the intended recipient's original transplant procedure;
- Develop, implement and comply with a procedure to verify stored donor extra vessel information such as the donor ID, container contents, extra vessel expiration date, ABO, all serologies with the recipient's ABO and serologies prior to implant into a secondary recipient;
- Maintain documentation that the verification has taken place and make this documentation available for audit.

The DEQ staff may detect potential violation of this proposed policy by:

Collaboration with the UNOS Research Department to generate monthly reports which identify situations where hepatitis positive vessels were used in a transplant procedure in a secondary recipient other than initially intended.

Upon review, if non-compliance with the hepatitis positive vessel storage and transplant policies is identified, DEQ will investigate through the use of formal correspondence to gather case details. All potential violations of vessel policy will be forwarded to the Membership and Professional Standards Committee (MPSC) for review in a blinded fashion.

Policy or Bylaw Proposal:

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).
- The vessels must be stored in a rigid, sterile sealed container labeled with the recovery date, ABO, serology, 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.
- 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.