

Operations and Safety Committee: Proposed Recommendations for Policy Regarding Vessel Storage and Transplant

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Background

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 inadvertently transplanted into a living donor liver recipient that was hepatitis C negative. 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.

Options Considered by The Committee

- Separate storage refrigerator for HCV (+)/HBV surface antigen (+) extra vessels - *Not a feasible option: costly and difficult for programs to implement;*
- Special labeling for HCV (+)/HBV surface antigen (+) stored extra vessels – *proposed for June 2011 Board with requirement of use for the intended recipient only. Board asked committee to reconsider its recommendation for storage;*
- Prohibiting storage of HCV Ab (+) and HBV surface antigen (+) extra vessels – *proposal before the Board*

HEPATITIS POSITIVE EXTRA VESSELS TRANSPLANTED 2008-2009

Transplanted into...	HCV+	HBV Core+	High Risk
Same Recipient as Solid Organ	20	33	122
Another Recipient	4	4	22

- There were **4** Hep C+ vessels transplanted in “secondary” recipients during this timeframe:
 - ✓ Two recipients Hep C – and two Hep C + pre-txp
 - ✓ Of the 4 events, **one** resulted in **confirmed transmission**.
 - ✓ **2** hepatitis C + vessels txp'd in hepatitis C – recipients with no transmission - **near misses**.
 - ✓ There were **no reports** of HBV Surface + vessels transplanted into a secondary recipient.

Note: **4** HBcAb + donor extra vessels transplanted into secondary recipients during this timeframe.

Vessel Supply & Demand Analysis Results

- Results: Analysis showed that it is likely that about 1 DSA would experience a vessel shortage with a one year period of time.
- Conclusions: Widespread shortages are unlikely, though a small number of shortages could theoretically occur.
 - If a shortage occurs, sharing of vessels between centers and synthetic vessel substitutes can be used (although inferior to donor vessels).
 - The benefits of prohibiting storage of these vessels outweighs the potential for disease transmission, since widespread shortages not expected.

RECOVERED VESSELS BY DISPOSITION

2008-2009

	Reported Outcome of Vessels								
	Transplanted Into Same Recipient		Transplanted Into Another Recipient		Reported Destroyed		Status Not Yet Reported		
	N	%	N	%	N	%	N	%	
Year									
2008	851	12	115	1.6	2,325	32.7	3,810	53.7	
2009	862	12.2	97	1.4	2,480	35.1	3,631	51.4	
Total	1,713	12.1	212	1.5	4,805	33.9	7,441	52.5	

- Disposition not reported for **52.5%** of vessels.
- Of vessels w/ reported disposition, **29%** were transplanted.
- Of transplanted, **11%** went to a “secondary recipient.”
- Under-reporting is identified, likely substantial for near misses or potential disease transmission that may have gone unrecognized.

OPTN Committees' Response to Vessel Proposal

Opposed:

Liver/Intestine

Pancreas

Peds

POC

TAC

Minority Affairs

Supported:

DTAC

LDC

OPO

TCC

PAC

Regional Response to Vessel Proposal

7 - Opposed:

Region 1

Region 3

Region 4

Region 7

Region 9

Region 10

Region 11

4 - Supported:

Region 2

Region 5

Region 6

Region 8

Individual Responses...Opposed

- HCV - most common indication for liver transplantation - use of vessels after a txp, necessitating storage, is rare but it does occur.
- Having access to vessels can be both graft and life saving.
- Prohibiting storage forces use prosthetic material with higher risk of infection and thrombosis or list the patient for re-transplant.
- Rules for labeling, color coded storage containers or alternate storage areas are preferable, HCV infection is not desirable but informed consent should be the criteria for use or disposal.
- Limit the use of vessels to the primary organ recipient

Individual Responses...In Support

- Modest correction to the inappropriate designation of blood vessels, should be regulated under 21 CFR 1271 eliminating this problem.
- No one would want to use vessels from a donor with a high risk of transmitting an infectious disease, proposal is entirely appropriate.
- Organs from a hepatitis C + donor for a hepatitis C + recipient are used, this level of risk is never indicated in the use of donor blood vessels given the likely supply and demand for such tissue.
- The proposed practice is the safest option for all involved, to not store these vessels.

Professional Societies' Response

ASTS - OPPOSED –

- Reaction to one case of transmission occurring prior to new labeling policies;
- Vessels are needed to rescue the organ or patient when there is a vascular complication. Multiple cases have arisen where patients have needed vessels and were not available, whereas disease transmission has occurred once; The proposal is designed to improve patient safety but may create more situations where patient safety is at greater risk.
 - *HCV transmission in 2009, 2 near misses of HCV transmission, it is likely that under-reporting of extra vessel disposition lends to under acknowledgement of other transmissions or near misses.*
- Transplant of HCV + organs is allowable, storage of the HCV + vessels should be allowable;
 - *The storage aspect of extra vessels makes extra vessels different from solid organs especially in regard to tracking disease transmission.*

NATCO - SUPPORT –

- Ensures that the accidental use of HBV + and HCV + vessels does not occur; Requiring verification and labeling information ensures that those who have access or handle vessels, have full disclosure of information.

Resolution 10

POLICY 5.10.2 Vessel Storage -

- Prohibit storage of HCV Ab positive and HBV surface antigen positive extra vessels.

POLICY 5.10.1 Vessel Transplant –

- Remove requirement for implanting TXC to provide detailed explanation to OPTN when hepatitis + vessels are transplanted into a secondary recipient .

Questions?

