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

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Chair, Operations and Safety Committee

OPTN/UNOS Board Meeting
November 14 - 15, 2010
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

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.

<table>
<thead>
<tr>
<th>Transplanted into...</th>
<th>HCV+</th>
<th>HBV Core+</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Same Recipient as Solid Organ</td>
<td>20</td>
<td>33</td>
<td>122</td>
</tr>
<tr>
<td>Another Recipient</td>
<td>4</td>
<td>4</td>
<td>22</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Year</th>
<th>Transplanted Into Same Recipient</th>
<th>Transplanted Into Another Recipient</th>
<th>Reported Destroyed</th>
<th>Status Not Yet Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>2008</td>
<td>851</td>
<td>12</td>
<td>115</td>
<td>1.6</td>
</tr>
<tr>
<td>2009</td>
<td>862</td>
<td>12.2</td>
<td>97</td>
<td>1.4</td>
</tr>
<tr>
<td>Total</td>
<td>1,713</td>
<td>12.1</td>
<td>212</td>
<td>1.5</td>
</tr>
</tbody>
</table>

- 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

OPTN
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.

OPTN
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?