

OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
March 10, 2015
Conference Call

Daniel Kaul, MD, Chair
Cameron Wolfe, MD, Vice Chair

Discussions of the full committee on March 10, 2015 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov/>.

Review of Public Comment Proposals

1. Address Requirements Outlined in the HIV Organ Policy Equity Act (OPO Committee)

The Committee Chair, who also serves on the joint subcommittee that provided expertise to the sponsoring committee.

A member asked if HIV positive donors with co-infection of Hepatitis C were prohibited from the study. Committee members who have also participated in the HOPE Act work group noted that there is no specific prohibition of donors that have been made available to the public at this time. Unless this is included in the National Institutes of Health (NIH) research protocol, this is anticipated to be left to medical judgment. Changes to HCV treatment may also change the opinion and acceptance of using organs positive for this disease overall.

After review of the slide presentation, Committee members noted no concern related to the progress of this project or the plan outlined within it. Members eagerly await the release of the NIH research protocol that will outline specific requirements for both donor and recipient selection.

2. Modify Sterile Internal Vessels Label (Operations & Safety Committee)

The Committee liaison presented this proposal on behalf of the DTAC's crossover member to the sponsoring committee who was unable to attend the full teleconference.

Committee members spent considerable time reviewing the current internal label versus the proposed simplified version of this label. It was suggested that the new proposed label would raise caution that would then send the transplant professional back to the more detailed poly-plastic hang tag label that is attached to the outermost bag of the triple barrier in which the vessel container is stored while refrigerated. This hang tag includes a breakdown of individual tests rather than the larger Hepatitis B, Hepatitis C, and HIV categories on the proposed label.

Committee members are concerned that results such as a positive Hepatitis B surface antibody result could be misconstrued using this new simplified label. This could also be the case for a label marked positive due to a donor's Hepatitis B core antibody result, as current policy does not prohibit storage and use of the vessel. The Committee suggests that the Operations & Safety Committee consider leaving more detailed check boxes specifically for Hepatitis B on the internal label. The Committee believes that specifically listing options for surface antigen, core antibody, and surface antibody may be of more clinical value in this setting.

The Committee also emphasizes that the policy cited at the bottom of the draft internal label does not currently include any references to positive nucleic acid test (NAT) results. This language was approved by the Board in November 2014, and will be implemented when the testing requirements for both living and deceased donors are implemented this summer. Committee members believe it is important to highlight that vessels found to be NAT positive be treated in the manner required by policy currently during this interim period.

Other Significant Items

3. Case Review

The Committee reviewed and classified eleven potential donor-derived disease transmission events. The Committee did not complete its full agenda of case review due to prolonged discussion regarding two cases that were interrelated. Committee members requested CDC assistance on completing additional testing to resolve two of these cases. The balance of incomplete cases will be carried over to the March 24, 2015 conference call agenda.

Upcoming Meetings

- March 24, 2015 case review call
- March 31, 2015 in-person meeting (Chicago, Illinois)