

OPTN/UNOS Operations and Safety Committee
Meeting Summary
December 16, 2014
Conference Call

Theresa Daly, Chair
David Marshman, Vice Chair

Discussions of the full committee on December 16, 2014 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>.

Committee Projects

1. Proposal to Modify ABO Determination, Reporting, and Verification Requirements

The Committee considered a revised proposal to modify ABO determination, reporting, and verification requirements. A public comment proposal originally went out during spring 2014 public comment. It generated significant debate and was tabled after lengthy discussion at the OPTN/UNOS Board of Directors (BOD) meeting in November 2014. Modifications to the proposed language were made based on member discussions on the December 2, 2014 OSC conference call. Proposed changes to the original policy language were reviewed with members. During this call, it was clarified that this proposal would have the on-site recovering surgeon participate in verifying donor and organ information and that only the OPO would be responsible for verifying recipient information when the intended recipient is known to match with CMS rules. This issue caused great debate during public comment and at the BOD meeting. OSC surgeons agreed that these changes were clear and reflected previous decisions made. The Committee unanimously approved sending the proposal to the Policy Oversight and Executive Committees for January-March 2015 public comment consideration.

The Committee discussed requirements developed for second user verification of subtype. Second user verification for initial reporting of blood type is currently programmed and functions to support existing policy. Currently, all UNetsm systems and KPD allow for one user to change primary blood type A or AB to one with a subtype (A to A₁ or A₂; AB to A₁B or A₂B). Policy requires a second user verification, however, the current computer system functionality does not enforce this unless both a primary and subtype choice is made at first data entry. The system as it currently functions offers two paths and one does not require second user verification of subtype. Requirements have been developed that would always require second user verification of subtype. Matches could still be run using primary type following second user verification. These new requirements would necessitate second user verification for subtype prior to running a match which uses subtype in the allocation algorithm.

The requirements originally included collection date and time of blood type results. The Committee decided to drop these fields due to concerns over potential data entry errors, the cost and resources required for limited benefit, and the adequate existing use of source documents for proof upon survey.

2. Modify the Sterile Internal Vessels Label

The Committee discussed two options for modifying the sterile internal vessels label. The goal is to reduce potential data transcription errors on this small label that must be completed by hand in a sterile field while not compromising the management of identification and critical information that could impact patient safety.

Data reviewed by the OSC showed significantly increasing rates of vessels from donors who are either hepatitis C (HCV) positive and/or at US PHS increased risk for human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV). The Committee has decided to keep two questions on the sterile internal vessels label addressing donor status on these items. Following discussion, the Committee agreed they would like to include some message that conveys the policy prohibition of storing donor vessels positive for HCV or HBV surface antigen (HBsAg). HOPE Act proposed policy will also prohibit storage of HIV positive vessels if passed. The Committee also endorsed that the label contain a message to direct the user back to source documents for infectious disease results. The sterile internal vessels label will contain an indication if any results are positive for HIV, HBV, or HCV, however, the user will need to consult source documents for details. The Committee will continue reviewing label drafts via email for the version that will be used in the public comment document. The requested changes made during the conference call will not impact the proposal policy language.

The proposed policy language that would reduce required infectious disease testing information down to whether the vessels are from a donor positive for HIV, HBV, or HCV was reviewed with the members. The language only impacts the sterile internal vessels label and policy requirements for the hangtag poly-plastic vessels label will remain unchanged. The Committee voted unanimously to send this proposed language and a draft label to be finalized via email for January-March 2015 public comment consideration by the Policy Oversight and Executive Committees. The public comment document will seek feedback on whether surface antigen versus core positive for HBV should be denoted on the label as this impacts whether the vessel can be stored.

3. Improve Transport of Living Donor Organs

The Living Donor and Operations and Safety Committees will be restarting a project to examine living donor organ transportation in 2015 using a Health Care Failure Modes and Effects Analysis exercise to identify potential fail points. Two OSC members have agreed to serve on this project and more volunteers would be welcomed.

4. Develop a System to Share Patient Safety Events and Information

The Patient Safety Advisory Group of the OSC will begin meeting on a monthly basis starting January 22, 2015.

Upcoming Meeting

- January 27, 2015 (teleconference meeting)