

OPTN/UNOS Operations and Safety Committee
Meeting Summary
December 2, 2014
Conference Call

Theresa Daly, Chair
David Marshman, Vice Chair

Discussions of the full committee on December 2, 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 received an update regarding the OPTN/UNOS Board of Director's meeting in November 2014 where the OSC Proposal to Modify ABO Determination, Reporting, and Verification Requirements was considered but tabled. Several amendments that had been proposed at the meeting were shared. The Committee heard discussion around general issues raised at this meeting and discussed possible changes in response to the concerns. The Committee will vote on a proposal to send out for the first public comment cycle in 2015 at the next meeting on December 16, 2014. Following public comment, the proposal will be sent to the Board for reconsideration at their June 2015 meeting.

One concern raised during the Board meeting was the need to clarify that subtyping samples must be performed on pre-red blood cell transfusion specimens versus the current terminology, which states pre-transfusion samples. The Committee considered proposing a definition but agreed to use this term in the proposed policy. The Committee discussed other clarifications to subtyping language as raised at the Board meeting. It was also decided to update the 2011 OPTN/UNOS OSC guidance document published on subtyping to make sure all terms are consistent. An updated draft document will be taken to the Board at the same time for consideration with the ABO proposal.

The Committee heard and discussed points of concern regarding the proposed verification at deceased donor recovery and involvement of the on-site recovering surgeon. This discussion included that many had thought that verification of donor and organ information is already required in policy. The Committee heard about the opposition to having the on-site recovering surgeon participate in verifying recipient information when the intended recipient is known. CMS requirements were reviewed. The Committee decided to propose that the on-site surgeon be required to participate only in verifying donor and organ information.

2. Modify the Sterile Internal Vessels Label

The Committee discussed ongoing work and recommendations from the Electronic Tracking and Transport Project/Internal Sterile Vessels Label subgroup. The recommendations for consideration by the Committee included reducing the infectious disease information on this label to whether the vessels are from a donor positive for

HIV, HBV, or HCV. The subgroup recommended keeping on the data field that indicates whether the vessels are from a donor meeting the PHS Increased Risk guidelines. Supporting data regarding vessels disposition, frequency of infectious disease and high or increased risk status, and use in secondary recipients were reviewed. The Committee agreed with these recommendations and provided some suggestions for the draft label options discussed.

The Committee will vote on a proposal to send out for the first 2015 public comment cycle at their next meeting on December 16, 2014.

3. Infectious Disease Verification

The Committee discussed and agreed the recommendation to postpone sending this proposal out for public comment following the tabling of the ABO proposal and proposals from other Committees addressing infectious disease issues (HOPE Act and Re-Executing the Match When Serologies Change). The HOPE Act proposal will include required two-user verification for persons willing to accept HIV positive organs. In addition, programming will only allow allocation to recipients listed at transplant hospitals participating in IRB approved protocols meeting US Department of Health and Human Services criteria. The Committee felt that these two safety principles would provide initial sufficient safety mechanisms until the full infectious disease verification proposal that will now be planned for release during the second public comment cycle in 2015.

4. Electronic Tracking and Transport Project (TransNetsm)

The Committee received an update on the TransNetsm project. Voluntary OPO deployment is planned for March 2015. The project is working on the transplant hospital side of the application. The first successful field test in a transplant hospital occurred on October 9, 2014. An organ was scanned for receipt, recipient ID band printed, and the internal organ label and the recipient ID band were scanned and matched successfully. Future plans for transplant hospital testing and revisions as well as application availability for multiple platforms were shared.

5. 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. Volunteers are needed for the project. Two OSC members agreed to serve on this project.

6. 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)