

**OPTN/UNOS Operations and Safety Committee
Meeting Minutes
November 30, 2017
Conference Call**

**David Marshman, CPTC, BS, Chair
Michael Marvin, MD, FACS, Vice Chair**

The Operations and Safety Committee (Committee) met via Citrix GoToTraining teleconference on 11/30/2017 to discuss the following agenda items:

Public Comment Proposals: Discussion and Vote to Send to Policy Oversight and Executive Committees for January 2018 Public Comment

Proposal 1: Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB

Proposal 2: Extra Vessels: Reducing reporting burdens and clarifying policies

The following is a summary of the Committee's discussions.

1. Proposal 1: Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB

The OPTN policy development process was reviewed. The regional meeting process for discussion and consent proposals was reviewed.

Feedback from the Kidney and Minority Affairs Committee sought pre-public comment was presented. Changes made following the discussion at the in-person meeting were reviewed. Suggestions from work group subject matter experts (SME) and internal staff were reviewed. Narrative on the following issues has been revised:

- Neonate considerations were changed from suggesting having a policy to OPOs and transplant hospitals should consult with their blood banks and adjust practices accordingly because there are no OPTN policy requirements for having a policy on how to handle neonates. It was noted that the wording should be changed to strongly because many might not realize that this can have a major impact on results. It was noted that we do not want a recommendation that conflicts with policy (e.g. whether subtyping is required or not for neonates) that has subtyping requirements but that we might need to reconsider whether a policy addressing neonate is needed. If there were not a test that can provide accurate results for neonates, then this would be a reasonable consideration that can be documented on why subtyping cannot be completed.
- Added emphasis that choosing two like out of three subtyping results is not allowed due to this being a common issue found on site surveys
- Added one clarifying sentence regarding the event that the donor has received a RBC in the past (not during the current hospitalization) then the OPO must determine the time if any that they consider safe to perform subtyping (regardless of hemodilution status)
- Put all key points into summary at the front
- Added reference to liver policy that adds points when subtyping is performed

The Committee voted unanimously to approve submitting the proposal for public comment.

Next steps:

The committee will submit the proposal for Policy Oversight and Executive Committee consideration to send out for January 2018 public comment.

2. Proposal 2: Extra Vessels: Reducing reporting burdens and clarifying policies

The OPTN policy development process was reviewed.

The following proposal changes following the in-person meeting discussions and internal review were highlighted regarding extra vessels:

- It was clarified that IT programming for a drop down for infectious disease tests is not feasible due to uploading issues. The Committee will get feedback on what individual tests need to be added to DonorNet during public comment.
- Definition for extra vessels has been revised for clarity and brevity.
- Exceptions to HIV screening requirement were made but clarified that results must be obtained prior to storing, sharing, or using
- Do not need to document abnormality or have specific tissue typing requirements
- Extra vessels may only be recovered with one organ. The authorization sections (deceased and living) specify that their use is for transplant.
- When an organ has been shipped but then released back to the OPO and extra vessels were with the organ, then the extra vessels will go where the organ is reallocated. If extra vessels are not used for transplant with the organ that they were recovered with, then the reallocation is done by the transplant hospital and in this situation the extra vessels do not go back to the OPO.
- Elimination of vessels language from liver policy regarding splitting
- Duplicative areas in policies 14 (living donor) and 16 were cleaned up
- Increased risk consent is required but in emergent situations the transplant hospital can use extra vessels from an increased risk donor and then inform the recipient afterwards and do follow up testing
- Removal of policy on OPO reasonable efforts for timely packaging as this is not enforceable
- Adding specific transport container phrase where needed
- Label (polyplastic) will require HIV, HBV, and HCV tests only versus current “all”
- Showing where language will add “extra” or delete “vessels”
- Verification policies were combined for deceased and living donors. The only substantive change is to verify HIV, HBV, and HCV infectious disease results versus all infectious disease results. Results received post-transplant have policies that do apply to extra vessels.
- Authorization requirements moved to policy 2 (deceased) and policy 14 (living)
- Reviewed changes to sharing requirements. Moved language up regarding restrictions on living donor extra vessel use.
- Seven day reporting requirement for use, sharing, or destruction

The Committee voted unanimously to approve submitting the proposal for public comment.

Next steps:

The committee will submit the proposal for Policy Oversight and Executive Committee consideration to send out for January 2018 public comment.

Upcoming Meeting(s)

- December 28, 2017 Teleconference