

**OPTN/UNOS Operations and Safety Committee
Meeting Minutes
February 2, 2017
Conference Call**

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

Introduction

The Operations and Safety Committee (hereafter, the Committee) met via Citrix GoToTraining teleconference on 02/02/2017 to discuss the following agenda items:

1. Infectious Disease Verification (IDV) Proposal
2. TransNetSM Clarification
3. Vessels Clarification
4. Item 23 Data Request: Extra Vessels Reporting Evaluation
5. Patient Safety Advisory Group (PSAG) Update

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

1. IDV Proposal

The Policy Oversight Committee (POC) had a split vote on the modified IDV proposal that was supposed to go out for public comment in January, and the Committee's leadership decided to pull the proposal before review by the Executive Committee. The Committee discussed whether to go forward with the project for the next public comment cycle, and what the scope of the project should be.

Summary of discussion:

Committee leadership felt that some of the POC comments incorrectly focused on the substance of the proposal, but the comment of not involving the American Society of Transplant Surgeons (ASTS) would be considered a valid point by the Executive Committee. POC members indicated that the Committee should have reached out to ASTS before going forward with the proposal. ABO implementation was another concern raised by POC members. The continued concern over ABO implementation has impacted current efforts of the Committee to address IDV. A Committee member noted that divorcing the proposal from the ABO process might provide more support from the proposal. Another Committee member noted that is exactly what the revised current proposal sought to do by allowing latitude and focusing only on living donor pre-recovery requirements.

A Committee member suggested that they would be willing to reach out to ASTS leadership as they might have a greater appreciation for a proposal that reduces the likelihood of disease transmission. The Committee discussed reaching out to the joint societies and POC members individually to prepare for the next public comment cycle and to create more support for the proposal going forward. The Committee decided to engage further both the Ad Hoc Disease Transmission Advisory Committee (DTAC) and the Membership and Professional Standards Committee (MPSC). The MPSC originally referred the IDV issue to the Committee, and thus it makes sense to have a dialogue about expectations and next steps with them. A Committee member mentioned the Liver Committee as another possible stakeholder given the developments in hepatitis treatment and use of positive organs. The June OPTN/UNOS Board of Directors meeting will also provide an opportunity to have informal face-to-face discussions.

The Committee discussed whether to have the policy apply to just living donor (a feature of the proposal pulled before the Executive Committee) or to include deceased donors as well. Committee members expressed support for doing both, given the greater time frame to prepare the proposal (until mid-June), a desire to not address the project piece-meal, and the parallel structure between living and deceased donors. Other Committee members were concerned about the operational impact on the OR and surgeons. Living donor allows a greater time period for IDV verification than deceased donors. The lack of time in the OR creates a problem if the policy would apply to deceased donors as well. The Committee decided to let the IDV Work Group continue to work on deceased donor language and bring the results back to the Committee to evaluate.

Next steps:

The UNOS liaison will reach out to MPSC and DTAC for opinion and potential support in redesigning the IDV proposal going forward. The IDV Work Group will continue to work on deceased donor language and bring the results back to the Committee to evaluate.

2. TransNet Clarification

The Committee reviewed the policy language and the next steps for a policy clarification to the TransNet implementation that delays the requirement for mandatory TransNet usage for VCA deceased donor organ labeling and packaging until November 1, 2017.

Summary of discussion:

The UNOS liaison reviewed the background behind sending a clarification to the Executive Committee to delay the implementation of mandatory TransNet usage for VCA deceased donor organ labeling and packaging. IT is unable to finish its programming before the deadline of June 1, 2017 for VCA and import donors. VCA, compared to import donors, is relatively small and delaying its implementation will have less of an impact than delaying import donors. Because the date is being changed for VCA compliance with TransNet, the Committee is required to send a clarification to the Executive Committee.

The Committee reviewed the policy language, which the UNOS liaison noted may need to be modified to clarify that the implementation change includes “VCA donor organs *and accompanying extra vessels, tissue typing materials and documentation*” (italics language not currently in the mini-brief). OPOs will still be required to use TransNet for labeling and packaging all other deceased donor organs at the original implementation date of June 1, 2017.

Next steps:

The TransNet mini-brief will be on the agenda for the February 27th Executive Committee call. The Executive Committee will decide whether to approve the change on behalf of the Board of Directors.

3. Extra Vessels Storage: Clarification

The Committee discussed another change that the Executive Committee will evaluate at its February 27th call to clarify that reporting language covers all vessels (not solely stored vessels).

Summary of discussion:

The original WaitlistSM removal programming (2006) and subsequent TIEDI[®] extra vessels reporting programming (2015) communications have indicated that all vessels dispositions must be reported. Some members and staff interpret the policy to apply only to stored vessels since the reporting language is in the stored vessels section of policy. An issue that prompted the clarification is that some programs are selecting “no” or “unknown” for whether extra vessels are used in the mandatory field at Waitlist removal. This field must be filled out within 24 hours of

candidate removal from the list. Selecting “no” or “unknown” at Waitlist removal does not necessarily provide a final disposition. These cases cascade over into an expected data list in the TIEDI® extra vessels reporting system released in 2015. There are questions whether a final disposition is required in some cases such as extra vessels destroyed in the OR. It is an issue in that it leaves a gap in vessels disposition reporting. It is important to have a final extra vessels disposition for disease transmission reporting purposes.

Although the change is being proposed as a clarification, some see the change as substantive. They are not convinced that the TIEDI communications show the policy was intended to apply to all extra vessels. In this view, programs are not out of compliance if the vessels disposition occurs in the OR. A Committee member noted that the clarification would not change behavior. UNOS staff agreed, but suggested that it does not represent a best practice to assume what happens to the extra vessels if they are marked as “unknown”.

A Committee member suggested it may be simpler to remove “unknown” as an option for the Waitlist removal extra vessels question. The member suggested that the person filling out the mandatory Waitlist removal questions would be forced to talk to the surgeon relatively soon after the operation, when the surgeon would still remember how the extra vessels were disposed. However, another Committee member noted that this creates a problem from an operations perspective, because there could be situations where trying to get verification from the surgeon may lead to a patient being removed from Waitlist after the 24 hour requirement. The Committee agreed that was a bad outcome to be avoided if possible.

The Committee discussed scenarios in which a program uses some of the extra vessels but not all, leaving some left over. A question of “did you use the vessel” as it currently stands does not capture whether all of the vessels were used. The Committee also discussed whether verification needs to include asking whether vessels were stored AND used.

The clarification that the Executive Committee will consider would go in Policy 16.6.A, which currently says that vessels dispositions must be reported within seven days of use or destruction of vessels. The clarification is planned to include policy cleanup of a justification that is outdated. While changing the question in Waitlist removal would solve one problem, it creates one of differing timeframes because vessels dispositions must be reported within seven days, and Waitlist removal must be reported within 24 hours.

Next steps:

The Committee will work with the MPSC and member quality staff to prepare the vessels mini-brief for the Executive Committee.

4. Item 23 Data Request: Extra Vessels Reporting Evaluation

The Committee reviewed the plan for monitoring compliance with extra vessel disposition reporting.

Summary of discussion:

UNOS staff reviewed the 2015 evaluation plan for TIEDI. A UNOS staff member recommended capping the data request for the year of 2016, then subsequently adding six months at a time. The requirement for the Committee to request data to assess the number of extra vessels recovered for transplant, those reported as transplanted or disposed, and extra vessels usage reported at the same time of Waitlist removal or via email to data quality is feasible according to UNOS staff. Potentially, the Committee could take a deeper dive into extra vessels dispositions that were reported more than seven days out from transplant or disposition, and those stored more than 14 days after recovery. Another opportunity would be to look at the number of extra

vessels whose disposition has not been reported after 21 days of donor recovery (14 days after recovery plus 7 days reported after transplant or destruction).

A Committee member expressed interest in visualizing the data through Tableau, and the UNOS presenter was receptive to looking into the possibility of using Tableau.

The other “deeper dive” the Committee could go into would be looking at those extra vessels reported as transplanted, specifically, the number of transplants into primary recipients compared to other “secondary” recipients. The Committee discussed requesting data on extra vessels transplanted into indexed versus non-indexed patients. A Committee member suggested that this data would be useful in showing how valuable these vessels are and illustrating that the benefit of the vessels far outweighs the small risk of disease transmission. UNOS will provide data on the distribution of extra vessels after the donor recovery: the number of times the vessels were used in a patient and when they were used. The use of these vessels is so important because there often is no viable alternative except a graft, which has a much higher incident of clotting.

The Committee also discussed looking at the data by center and where the sharing occurs. Previously, the Committee examined data showing the relative frequencies of how many hospitals used extra vessels in secondary recipients. The data showed that 63 hospitals used extra vessels in secondary recipients 1-3 times within the time period. Three hospitals used extra vessels in secondary recipients over 50 times during the same time period.

The Committee discussed the difficulty of trying to track extra vessels when the reporting does not capture whether there are multiple dispositions for extra vessels coming from the same donor. However, a Committee member noted that most of the time the extra vessels are not even opened on the recipient end, and commented that the reporting process for tracking multiple dispositions of vessels would be prohibitively complicated.

Next steps:

UNOS staff will start writing the data request, which will be ready in time for the in-person meeting.

5. Patient Safety Advisory Group (PSAG) Update

The Committee briefly reviewed the Extra Vessels Instructional Innovations project currently in development. The project is slated for release in February 2017. The Patient Safety Advisory Group (PSAG) has designed different scenarios to educate the community about issues relating to extra vessels and their storage. The project utilizes non-identifiable aggregate information from patient safety investigations in areas covering extra vessel storage issues related to HCV positive vessels. The product covers scenarios where issues might occur (staff transitions) and goes into standard operating procedures and best practices.

Next steps:

The Extra Vessels Instructional Innovations project will be done before the Committee’s in-person meeting in March.

Upcoming Meetings

- March 2, 2017 (teleconference)
- March 28, 2017 (Chicago)