

**OPTN/UNOS Operations and Safety Committee  
Meeting Minutes  
May 24, 2018  
Monthly Conference Call**

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**Introduction**

The Operations and Safety Committee (OSC) met via teleconference on 05/24/2018 to discuss the following agenda items:

1. Introductions and Announcements
2. Recovery Date Project
3. TransNet Extra Vessel Label Recommendations
4. Patient Safety Advisory Committee (PSAG) Update and Recommendations
5. Other significant items

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

**1. Introductions and Announcements**

Summary of discussion:

The OPTN/UNOS Board of Directors (BOD) Policy Group 3 met on May 21, 2018 and unanimously approved both the ABO subtyping guidance and extra vessels proposals. Both were also recommended for the consent agenda.

Next steps:

Consent agenda items will be presented at OPTN/UNOS BOD meeting open session on June 11, 2018.

**2. Recovery Date Project**

There is only a short time period to work on the proposal to send out for public comment related to recovery date.

Data summary:

1. What we know:

Recovery date is the date of donor operating room (OR) entry. The current definition on the deceased and living donor forms is in the help documentation only. From the Organ Procurement Organization (OPO) perspective, basing the date on OR entry creates data issues. The OPO tracks donors based on date of OR entry to match data for UNOS reporting, but then most OPOs track it based on date of cross-clamp, creating nuances in data.

With transplant hospitals, based on feedback through TransNet Work Group, as well as through public comment, this data issue is leading to programs having late destruction and/or reporting of extra vessels because of the data issues. The dates can reflect the date of OR entry in Transplant Information Electronic Data Interchange (TIEDI) but on the extra vessels label it is reflecting the date of cross-clamp. Dates are different 6% of the time and when the cross-clamp occurs after midnight following OR entry. The goal therefore is to make the recovery date align with the cross-clamp date and build it into the policy.

## 2. Evidence of issue:

The data shows evidence of the problem. Extra vessel policy applies to both deceased and living donors. The recovery date (or a similar term) is also used in policy for other time frames for reporting, as well as some allocation requirements. The other policy implications have to be taken into consideration moving forward when proposing changes.

## 3. Other Committee stakeholders:

OSC leadership met with the OPO Committee leadership, who took this to the OPO Committee. The OPO committee is very supportive. OSC leadership also met with the Data Advisory Committee (DAC) leadership, who are also very supportive, and will talk about the potential proposal at their next meeting very soon. Other committees which may be stakeholders include the Living Donor Committee and Vascularized Composite Allograft (VCA) committee. Discussions will begin to solicit feedback from the VCA Committee.

It is known that some extra vessels are stored more than 14 days beyond the recovery date. There was a downward trend in this in 2017, but spiked in the 4th quarter. The median number of days past 14 days of storage was 1 day. It is likely the root cause is the misalignment of dates. By aligning dates, data storage issues can be prevented.

## 4. Analysis Plan:

The Committee discussed other analysis needs: These include the following questions:

Where else in UNet might be impacted? What else is impacted when we talk about research and data reports? Is there impact to the Scientific Registry of Transplant Recipients (SRTR)? What are current and future states regarding IT programming when entering data and performing updates? Is there impact regarding Centers for Medicaid and Medicare Services (CMS) requirements and the data collected? How would it change the data entry workflow for OPOs as they put that data in and manage their labeling processes? What other outlier situations could be impacted by the potential change? Are there other current policy or date requirements that need to be considered? Are there any other alternatives?

An internal UNOS staff team has been meeting weekly to work through the analysis plan.

## 5. Outliers:

There are several outlier situations that need to be considered during the proposal development.

**Extra Vessels:** Living donors are included here although there are very small numbers. During the past two years (2016-17), three sets of extra vessels were recovered from living donors and one set was transplanted. Another 406 living donor transplants used extra vessels from a deceased donor.

**DCD Donors:** DCD donors comprised 17% of deceased donor cases. There were 1,214 cases of extra vessels recovered from DCD donors (1,050 unique donor identifiers) and 29.4% of all DCDs had extra vessels removed. Of these, 169 were transplanted and 1,028 were destroyed. Would DCD have different definition of recovery date?

**Clamp Date:** There were 14 cases with missing clamp dates for deceased donors (0.069%). There are a small number (n = 4) of missing clamp dates for extra vessels (3 recovered and 1 recovered from a donor who died outside of U.S.).

**VCA:** VCA does not have an obvious way to identify extra vessel usage, but further research is being done. There were 13 VCA transplants in 2016 and 6 in 2017. As VCA transplants increase, what can the system do in the future?

## 6. Definitions for deceased and living donors in the help documentation:

There are two definitions. For the deceased donor, it is the date the donor entered the operating room for the purpose of organ recovery and then recovery date for living donors is the date the donor organ was recovered. They are the same concept.

In extra vessels policy, the recovery date goes on the labels for both rigid container and the outermost layer of the triple sterile barrier. This is the recovery date that has raised the question about the labels having a different recovery date than the date that is in TIEDI. TIEDI pulls the recovery date entered by the OPO to calculate dates defined in policy for destruction of unused extra vessels within 14 days after recovery date and reporting within 7 days of the final disposition.

There are additional places where recovery date or procurement date is used. For VCAs data submission by OPOs must be completed 30 days after procurement date. The deceased donor organ disposition (DDR) form is required 5 business days after procurement date. Other times are in the living donor feedback form which is 72 hours after the donor recovery procedure and time prior to donation surgery. Living donor follow up forms are 60 days, 1 year and 2 years after the donation date. These policy definitions use either procurement date, recovery date or a similar term that will be evaluated. The DAC is planning on a comprehensive look at Policy 18 and these things would be included. The dialogue will continue in the future to ensure alignment.

Policy 18 deadlines also include additional living donor reporting based on organ recovery time that must occur for safety reports.

There are a few other time based requirements in policy. The start time for organ procurement is Policy 2.14.G, where there is a policy on agreeing on the start time for the procurement. Liver offer policy mentions when the match run can be regenerated. One reference is that the deceased donor liver has not been allocated within 2 hours of procurement. For liver segments in 9.8.A, it references the remaining segment has not been allocated by the time the deceased donor organ procurement has started. Then the organ offer limit is related to the pancreas and must be offered within 8 hours after procurement. This raises the issue of defining procurement and recovery.

Pre-recovery verification is used for when the host OPO must conduct the verification prior to organ recovery. What defines that organ recovery in this particular category?

## 7. Alternatives:

One alternative is changing the extra vessels policy expiration to be based on cross-clamp. The pro is this might be easier; the con is it may not solve the larger problem. The current extra vessels revised policy and label will be going to the OPTN/UNOS BOD June meeting. The words "clamp" and "cross-clamp" could be used to help with the outlier situations such as living donors. TransNet could upload real-time data entry for dates where appropriate. The group will look at what the alternative solutions are beyond just making the cross-clamp date equal recovery date as discussed.

## 8. Support:

It will be important for groups to see all the data. So far from discussions at TransNet, no additional feedback has been given, other than general support for the proposal.

### Summary of discussion:

The chair asked if it would be possible to compare how many extra vessels were stored beyond 1 day with data of cross-clamp versus data of recovery. This information may further validate the proposal. Research staff will look into conducting this analysis.

The group discussed clearly defining cross-clamp date for VCA, excision time or another term used for a specific instance so there is no confusion. The vice chair stated the terminology is key when looking at policies of recovery versus procurement. He made the analogy of if you have dinner reservations for 8 pm, you do not expect to be eating at 8 pm. Procurement might be set for 8 pm, but cross-clamp would be at 9:30. Procurement might be the term used for the entire episode of the OR where recovery would be clearly delineated as only once the organs are cross-clamped. Recovery date could be equal to cross-clamp and procurement would be the broader full procedure. The Committee was in agreement.

Staff asked if the term cross-clamp was only associated with deceased donors. For living donors, the term arterial clamp could be used. The committee agreed to use the term "cross-clamp" and define it as the cessation of arterial flow to the end organ.

In the TransNet call, it was mentioned there is still a date and time of cross-clamp in DCD cases. Although you have a date and time of cardiac arrest or cardiac death, the thought was that cross-clamp would still fit, so to keep it consistent rather than building an additional carve-out just for the 3,500 DCD donors or the 1,214 extra vessels. This should still be clear to all the OPOs. The Committee agreed to the use of one term no matter what the organ is or how the donor comes about.

Staff were asked about having TransNet populate the cross-clamp date into UNet. If TransNet fails, the OPOs still have to have the ability to override inside of DonorNet. Allowing for data to be entered one time only would reduce instances of two different dates and times and inconsistent entries. Staff will explore this option.

### Next steps:

The Committee will move forward to better define terms that are used and then clean up the recovery date aspect. All members will be kept up-to-date on internal analysis as the proposal is developed over the next 6 weeks.

The public comment proposal is due on July 10th. The Committee will need to vote on the proposal on June 28th or set up an additional meeting for that purpose.

## **3. TransNet Extra Vessel Label Recommendations**

### Summary of discussion:

Labels were discussed at the in-person meeting. Feedback included making PHS increased risk status more prominent in the process and making the storage message more prominent. Feedback was to tell users what they should do, so make it a very active voice and to put policy references last. Then move and reorganize so the related information is next to each other. Then three labels will be used with the larger font for the third label.

Staff discussed dialogue with the TransNet work group a week ago. Label recommendations need to be finalized by September 1st. The "use or destroy by" will say "do not store" on the first and third label was agreed to by the work group. There will also be a static message on the polyplastic label for when labels must be handwritten. PHS increased risk status will be more prominent and modeled after test results style. Language was changed to "transplant hospitals must not store if any results 2-8 are positive" and "If storage permitted, destroy within 14 days

after recovery date if not used". The current policy reference was removed and the Committee was in agreement.

Staff showed two language options for the third smart label. It will tell you to either "not store" or "use or destroy by" and then PHS increased risk: yes/no. One member pointed out that use or destroy by date may be confusing as to whether it must be destroyed on that date or used on that date. Wording could be changed to "no later" than including that date. The Committee was in agreement.

Another member asked about the "not positive" wording. It is not necessarily clear, but staff explained that policy does not specify "negative." For example, if a result is pending, then the extra vessels can be stored. This could be changed to extra vessels from donors "not tested positive." The member then asked what it would say if the results have not come back yet, and staff explained it would say "permit storage." Ultimately, the Committee decided to go with the language from the first mock-up of the third label.

#### Next steps:

Staff will send revised label mock-ups to the Committee via email.

The timeline goals are to have the design finalized by September, have the labels in the store by February, have the new TransNet app and some training in May, and then go live June 1, 2019.

#### **4. Patient Safety Advisory Committee (PSAG) Update and Recommendations**

Discussions on these items will be held off until a later meeting due to time constraints.

#### **5. Other significant items**

Any OSC members can listen to OPTN/UNOS BOD meeting.

Staff and some Committee members will be attending the upcoming American Transplant Congress (ATC). OSC has two posters on the safety data that will be presented. A member also recently presented the transportation poster at the Transplant Management Forum (TMF). There was interest at TMF and observers stated that they had not thought about many of the issues highlighted in the poster. Some were not aware the survey had been conducted. Based on feedback, lack of knowledge of transportation and insurance coverage is probably lower than survey results indicate.

#### **Upcoming Meeting**

- June 28, 2018: Monthly teleconference