

**OPTN/UNOS Operations and Safety Committee
Meeting Minutes
June 28, 2018
Monthly Conference Call**

**Michael Marvin, MD, FACS, Chair
Chris Curran, CPTC, CTBA, CTOP, Vice Chair**

Introduction

The Operations and Safety Committee (OSC) met via teleconference on June 28, 2018, to discuss the following agenda items:

1. Introductions and Announcements
2. Recovery Date Project
3. TransNet Extra Vessel Label Recommendations
4. Geography Update
5. New Project Ideas: HLA electronic data transfer, Transportation

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

1. Introductions and Announcements

Recent events

Committee members were briefed on recent events regarding liver allocation policies. Members were given background on the legal requirements for allocation policies under the National Organ Transplant Act (NOTA). The regulations developed for NOTA are referred to as the Final Rule. Under the Final Rule the Organ Procurement and Transplantation network (OPTN) the Board of Directors (BOD) is responsible for creating policies that have equitable allocation of organs. Geography is not to be a constraint except for certain reasons named in the Final Rule (e.g. avoid organ wastage).

The US Secretary of Health and Human Services (HHS), determines whether policies are consistent with NOTA. The secretary may provide comments to OPTN and if the Secretary concludes that a policy is inconsistent with NOTA, they can direct the OPTN to revise the policy. If it is not revised in a timely manner or it is still not consistent with NOTA, the Secretary can take other actions they deem appropriate.

Processes related to critical comments are named in the Final Rule in relation to the policies of how the OPTN is being operated. Any person can submit a critical comment to the Secretary. The Secretary will consider the critical comment in light of NOTA and the regulations, and may 1) reject the comment, 2) direct the OPTN to revise policies or practices consistent with the secretary's response, or take other action as deemed appropriate.

Since the last OSC meeting, there have been several notable developments related to liver allocation policy. There was a letter sent to the HHS Secretary involving liver allocation that is considered a critical comment. Then on June 8th, HHS sent a letter to the OPTN asking for opinions on some questions. The Executive Committee conducted an analysis and reviewed the questions. The Liver, Policy Oversight, and Ad Hoc Geography Committees weighed in. A finalized comment was sent back to HRSA on June 25th.

Content of letters and responses

The law firm, involved with the lung allocation issue last year, sent the critical comment. They argue that current and approved but not yet implemented liver allocation policy is inconsistent with the Final Rule because it uses regions and Donation Service Areas (DSAs). The letter challenges both the current policy and the policy that is approved, but not yet implemented, and the National Liver Review Board (NLRB) scoring of exception patients. It requests action by the Secretary to bring the policy consistent with the final rule.

On June 8th after HHS received this critical comment, the OPTN was asked to comment on four items regarding how the revised policy would be aligned with NOTA and the final rule. The Executive Committee, along with other Committees input, developed a response to the HHS Health Resources and Services Administration (HRSA) request.

The OPTN response was sent June 25th, stating liver does not include an over-reliance on DSA because medically-urgent candidates are prioritized outside of the DSA. Lung allocation policy was different in that it exclusively used DSA, but the revised liver policy does not. The OPTN further states that DSAs and regions are neither rationally determined, nor consistently applied. Furthermore the OPTN is committed to a multi-step plan to eliminate the use of DSAs and regions in liver distribution in a deliberative manner and within a timeframe that will reduce the likelihood of unintended consequences (e.g. organ waste and harm to patients).

On June 27th, the OPTN/UNOS President sent email communication to the transplant community. She urged the community to understand the seriousness of the critical comment and that the community must protect its ability to make decisions. The community also must understand that DSA and regions are not going to be an acceptable proxy for what is considered local allocation. The goal is to demonstrate that appropriate and quick, but thoughtful steps are being taken to rectify the situation.

Summary of discussion:

A member asked if the comment pertained to liver only. The critical comment was about liver only, however the impact and potential actions for other organs are being discussed. Any of the organ systems can be affected by lawsuits.

A HRSA representative reminded everyone that the Ad Hoc Geography Committee was intentionally made up of every organ-specific committee chair and vice chair. Every committee has been part of this discussion since it was initiated and they know this is coming.

The goal was to say a precipitous change could be more damaging than the good that the law firm is trying to do for the community. Also, the Executive Committee wanted to lay down specific steps that would be taken to implement a policy that replaces DSA and region with something that has a more rational, consistent basis. Another letter was received from the law firm yesterday critical of the OPTN's response to HRSA.

Next steps

- Executive Committee will direct liver only to review data and to come up with a public comment proposal that will go out in October and replace DSA and region with something to be determined. During regional meetings, three concepts of geography and what has happened to date with liver will be discussed.
- The public comment for liver proposal will be in October due to time needed for Scientific Registry for Transplant Recipients (SRTR) modeling to be done first (a minimum of 6 weeks). There will be a national webinar and potentially other options for feedback once a proposal goes out.

- The OPTN/UNOS BOD will adopt a replacement for DSA and region at meeting in December 2018 and it will be implemented in the matching IT system.
- Questions can be emailed to UNOS staff. There will be opportunity to discuss next steps at the fall cycle and then during public comment.

2. Recovery Date Project

Data summary:

At the last meeting, the plan was make fall public comment with a policy definition for recovery date equal to cross clamp date. Staff leadership felt there were too many issues with data policies (Policy 18). The Data Advisory Chair (DAC) and OPTN/UNOS President-Elect did support the OSC idea. UNOS staff saw that there were too many other implications and that this project would be better wrapped up in the overall rewrite planned for Policy 18 sponsored by DAC. DAC is supportive of incorporating the concept in their proposal, which would go out for spring 2019 public comment. While there will be a different sponsor and different timeline, the outcome should remain the same.

Next Steps:

The Committee will support DAC in this project.

3. TransNet Extra Vessel Label Recommendations

Data summary:

UNOS Professional Education will do print and story communication for the extra vessels policy changes going into effect on September 1st. OSC leadership and selected subject matter experts have reviewed the document created and it should be finalized by July 7th. Members were shown the education document and it will be posted on SharePoint so Committee members will have the opportunity to make further comments.

Some of the key points include:

- Extra vessels are the same as organs in policy, unless otherwise specified.
- Sharing requirements will change. Justifications will no longer be submitted. Disposition of sharing will be reported in TIEDI in 7 days if the transplant hospital sends extra vessels to another transplant hospital.
- Key facts about verification include Public Health Service (PHS) increased risk informed consent is required for a secondary extra vessel recipient, but the recipient can be informed after use due to an emergent situation with testing follow up afterwards.
- Things not changing include all specific references to extra vessels will remain in policy.
- Reporting timeframes are not changing.

Summary of discussion:

The Committee is close to finalizing extra vessels labels. In DonorNet[®], one can check "unknown" for the increased risk question. OPTN/UNOS Policy 2.4 states if the increased risk status is unknown or cannot be determined, then the person should be classified as increased risk. This is a small number of donors. The question would be whether there is a requirement for that question to be filled out in any phase of the donor process causing OPOs to choose the unknown category and then going back and correcting it.

Based on the small numbers, the Committee believes it would be a good idea to ask it to be removed, so it is not done in error. It could be that "unknown" is not allowed as a choice or a

warning is given that tells the user that "unknown is treated as yes". This can be done so the formatting would always be consistent.

The IT staff representative felt that adding a popup would not be consistent with the other fields on the screen. An easier solution would be to update the help documentation that coincides with the field. Just removing the unknown option would be clearest and most straightforward from the OPO side because they will probably select yes more times than not. The bigger confusion might be on the transplant program side interpreting unknown when they are in the blood banks and areas where extra vessels are stored.

Additional feedback from UNOS Member Quality on the label was to use the word "allow" versus "permitted". They were concerned that permitted and prohibited could be confused for one another. The TransNet label would read OPTN policy "ALLOWS" in all caps versus "permits." Also, where it says "DO NOT STORE," it will not say "use or destroy by." The Committee was in agreement with these suggested changes.

On the sterile extra vessels label, the word "EXTRA" would be added to the top and HBcAb would be changed to anti-HBc. When the label was revised in 2015, language was added to "check source documents for results". It could also be added that they could scan the barcode for results. A member noted that the barcode cannot be scanned from this label.

The chair reminded the Committee that this label is very small and wraps around the container of the extra vessels. It is also insurance if the extra vessels get separated from the internal label. Therefore, a user should not reference the scan because the external label will no longer be available to reference. Members agreed using the barcode and going back is a convenience, but one ultimately could go back to DonorNet and find it as well. They agreed to keep the label simple and not change the language to reference the barcode.

4. Geography Update

Not discussed at this meeting due to time constraints.

5. New Project Ideas: HLA electronic data transfer, Transportation

Summary of discussion:

Resources are subject to reallocation with the allocation changes. The vice-chair explained the idea is if you think about all of the mandatory things over the years, one that makes sense is to mandate that the human leukocyte antigen (HLA) data be electronically transferred. Many data points that are manually entered from HLA labs into UNet and HLA labs into their own systems should be automated with an interface. The potential patient safety gains by eliminating the manual process could be significant. This is one initiative being explored, but it may take a backseat to liver allocation requiring urgent IT efforts. The process would be long and require a lot of stakeholders.

The OSC and Histocompatibility Committee chairs met with UNOS IT staff in June during the BOD meeting. The Histocompatibility chair supports the idea as well. For their Committee, the next step is going out to public comment for repeat data entry into DonorNet and UNet for HLA results.

Next steps

- Meeting materials will be posted on the Committee's SharePoint site.
- The Committee thanked the current chair, David Marshman, for his great work. His term ends this month on June 30th.
- Michael Marvin, the current vice-chair will assume the role of chair and should be consulted for matters as needed.

Upcoming Meetings

- July 26, 2018 Teleconference
- August 23, 2018 Teleconference