

**OPTN/UNOS Operations and Safety Committee
In-Person Meeting Minutes
April 11, 2018
Richmond, Virginia**

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

Introduction

The Operations and Safety Committee (OSC) met in Richmond, Virginia on 4/11/2018 to discuss the following agenda items:

1. OPTN/UNOS Update
2. Policy Oversight Committee (POC) Update
3. ABO Subtyping Guidance
4. Extra Vessels Project
5. TransNetSM update
6. Patient Safety Data
7. Policy Evaluations
8. Patient Safety Advisory Group Update
9. Transportation Survey and other new project ideas

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

1. OPTN/UNOS Update

Summary of discussion:

The OPTN/UNOS Chief Executive Officer provided an update on geography, improving the efficiency of the allocation system, and potential committee restructuring.

An Ad Hoc Geography Committee has been formed with representatives from multiple Committees. The purpose is to develop principles that are consistent to become the basis of distance considerations for all organ allocations systems. Currently, there are some differences among organ allocation policies. One of their first tasks was to document current unwritten principles that do have impacts (e.g. allowable cold ischemic time which differs between hearts and kidneys for example). The Committee will be providing a report at the June OPTN/UNOS Board of Directors (BOD) meeting in June 2018.

Another effort out for public comment as a concept paper is looking at how the allocation system can become more efficient so that long match lists do not time out before organ placement. It was noted that the system does not require that every program get every organ offer every time. Conversely the system is not so narrow that a program is informed of which organ they will get for a specific candidate. The goal is to get somewhere closer to the middle. Modeling has been performed that can replicate the behavior and acceptance patterns down the exact donor and recipient for 95% of matches and transplants performed. The idea is to use this modeling to make the system more efficient. For example, if a program has never taken a Donation after Circulatory Death donor then perhaps they are not included on these matches. Although the system would have to find a trigger to re-include programs to account for potential or new acceptance patterns.

The other update item was on the potential restructuring concept that was also out for public comment. Due to public comment, an immediate change is not forthcoming but the structure

has never been evaluated. There will be a pilot developed as a proof of concept to create an expert council.

2. Policy Oversight Committee (POC) Update

Summary of discussion:

The Committee received an update on the Policy Oversight Committee (POC) from the vice chair who serves on this group. All vice chairs serve on the POC. Their job is to review all projects submitted by Committees. They do the following:

1. Assign the project to the correct primary strategic goal (1-5)
2. Continue to work towards alignment of the project portfolio with the OPTN Strategic Plan
3. Prioritize resources
4. Ensure collaboration with key stakeholders and provide feedback to sponsoring committees
5. Make a recommendation to the Executive Committee

The OPTN Strategic Plan designates the amount of resources that are targeted per goal (e.g. 40% of efforts for goal 1 which is to increase the number of transplants). It can be difficult to prioritize. The Committee recently heard the proposal for next OPTN Strategic Plan (2018-2021). The POC has reviewed and recommended seven new projects since October 2017. The POC also has reviewed and prioritized Goal 2 projects (equity in access) and in particular multi-organ allocation projects.

In May, the POC will review entire committee project portfolio (all ongoing projects). The current project alignment, displayed in a Tableau dashboard, was shown. Currently, public comment just finished for 12 proposals, including two OSC proposals (Subtyping guidance and Extra Vessels).

Next steps:

The Committee will continue to discuss POC updates at their in-person meetings or at other times as needed.

3. ABO Subtyping Guidance

The Committee considered public comments and a final version of the revised guidance proposal out for spring 2018 public comment ending March 23, 2018.

Data Summary:

The Committee was shown data that 538 donors were reported with a subtype in 2017, representing 3.3% of all blood types. Use of subtyped deceased donors since implementation of the new Kidney Allocation System (KAS) grew from 19 (pre-KAS 12/4/2013-12/3/2014) to 214 (2017).

Summary of discussion:

The Committee reviewed the following:

1. Public Comment Summary

2. Comparison between public comment version of guidance and post-public comment edits
3. Version of guidance if passed as proposed

The guidance document was well received during public comment. All regions supported the guidance as part of the consent agenda. The Kidney and Membership and Professional Standards Committees (MPSC) supported the proposal. Five professional societies: American Society for Histocompatibility and Immunogenetics (ASHI), American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), Association of Organ Procurement Organizations (AOPO) and North American Transplant Coordinators Organization (NATCO) expressed support for the proposal.

The Committee had asked for specific feedback on whether the document addressed concerns sufficiently. Two comments were discussed. ASHI had suggested consideration of the American Association of Blood Banks (AABB) standard that neonates do not fully express red blood cell (RBC) antigens until 2-4 years of age however they were in agreement with the guidance suggestion to consult with the local blood bank if that was decided. In fact, the Subtype Work group had specifically discussed the AABB recommendation and decided against use due to concerns that the top age would be used without enough evidence to do so thus limiting donors who would be subtyped. The Committee agreed with this decision.

The AST asked that the emphasis be on what not to do in subtyping. The Committee agreed and text was edited for the current version and bolded at the bottom of the key points section.

The Committee reviewed the following post public comment changes.

- Use of word “type” versus “group”
- Placement of key points only up front
- Bolding last key point and rewording what not to do
- Adding bullet to be careful not to confuse with Rh factor results
- Adding more bullets on common issues
- Adding additional package insert language and citations
- Rewording caution for “weak” results
- Editing for style/clarity

During the in-person meeting, the Committee made several additional edits to further clarify areas of confusion. The Committee voted (17 yes, 0 no, 0 abstain) to send the guidance document to the OPTN/UNOS BOD for consideration at their June 2018 meeting.

A situation where a transplant program completed subtyping after the Organ Procurement Organization (OPO) had completed subtyping was mentioned during the national public comment webinar. As part of the regional update, Committee members shared that this would be considered a discrepant result and then OPOs would need to allocate based on primary blood type. Follow up to this concern will be further discussed during the patient safety part of the agenda.

Next steps:

Send the guidance document “Guidance for ABO Subtyping Organ Donors for Blood Types A and AB” to the OPTN/UNOS BOD for approval and then distribution if approved.

4. Extra Vessels Project

The Committee considered public comments and a final version of the extra vessels policy and programming proposal out for spring 2018 public comment ending March 23, 2018.

Data summary:

The Committee reviewed data from the TIEDI[®] extra vessels disposition database. Between January 1, 2016 – December 31, 2017, 99.8% of donors with at least one organ reported as sent with vessels were reported in the database. A total of 19,248 dispositions were reported and 3,618 were used in transplant. Nearly 80% were reported as destroyed. Less than 1% were reported as sent to another hospital. Of the extra vessels transplanted in the two-year period, 2,801 were into the intended recipient and 710 were used in secondary recipients. Roughly 14% met criteria for Public Health Service (PHS) Increased Risk. Other factors such as late reports or storing prohibited extra vessels were reviewed. There was a relative decrease (11.6% to 8.6%) in extra vessels reported late from 2016 to 2017.

The Committee was shown data comparing cross-clamp versus recovery date data in DonorNet[®] and TransNetSM. The cross-clamp date is different than recovery date in 6% of cases in both DonorNet and TransNet. Dates varied more greatly in TransNet than in DonorNet. The date differences can cause issues with the expiration date of extra vessels.

Summary of discussion:

1. Public Comment Summary
2. Comparison between public comment version of policy proposal and post-public comment edits
3. Version of policy if passed as proposed
4. Draft of extra vessels labels

The proposal did well in public comment. All regions unanimously supported the proposal. The OPO Committee and the Ad Hoc Disease Transmission Advisory Committee (DTAC) supported the proposal. The MPSC supported the proposal but had some concerns. Five professional organizations supported the proposal (AOPO, AST, ASTS, ASHI, and NATCO). The Committee asked for specific feedback on what other infectious disease tests do OPOs perform due to travel history or local protocols that are not required by OPTN policy. The DTAC, AST, and Region 2 requested that Strongyloides be added to DonorNet.

The Committee discussed three public comment themes:

1. Concerns about transplant programs training and successfully implementing a TransNet scan
2. Suggestions to improve communications
3. Requests to revisit policies related to infectious disease verification and storage of extra vessel

The Committee discussed how transplant TransNet implementation might have challenges and potential strategies to address these concerns. In addition, policy will not mandate use. The scan will be one of three options (TransNet scan, DonorNet, or paper) to access infectious disease results not printed on the extra vessels label. The Committee will be programming OPO access to extra vessels data in order to help improve communications. The Committee did modify and clarify what infectious disease results do need to be verified for extra vessels when using in a procedure other than the original transplant where the extra vessels were sent with the organ.

The Committee discussed two additional concerns related to extra vessels that emerged in public comment: issues with the recovery date and extra vessels requested by transplant programs without being sent with an organ. Committee leadership discussed the recovery date concern with OPO Committee leadership. The issue is when the recovery date and cross clamp

date are not the same, then the transplant hospital can have issues with the vessels expiration date being miscalculated. Recovery date is not defined in policy but is defined in help documentation as the date the donor enters the operating room (OR). The plan is to develop a policy definition and define recovery date as the cross clamp date. Because of the potential data implications, this will not be made as a post-public comment change. The Committee plans to pursue a continuation project for fall 2018 public comment.

Another concern discussed was when extra vessels are requested for candidates, such as those that are scheduled to receive a living donor organ, outside of being sent with a recovered organ for an identified intended recipient. The Committee discussed this issue. OPTN/UNOS Policy is currently silent on the issue but staff had answered previous inquiries that there is no prohibition against this practice. The Committee discussed the proposed federal public comment when extra vessels for organ transplant were transferred from Food and Drug Administration (FDA) Health Resources and Services Administration (HRSA) authority. In this proposal, the HRSA written response indicated that they intended that the extra vessels could be used for living donors and other organ transplants other than the intended recipient but that they would not make the rules for these situations. The Committee decided to pursue a data request to identify the frequency of this occurrence and then identify next steps.

The Committee reviewed changes made post-public comment in response to comment or other analysis. They discussed further clarifying and moving extra vessels verification policy to the section for ABO verification. Additional edits for clarity were made. The Committee discussed and decided to remove the requirement for recipient infectious disease verification as it can give the false impression that positive extra vessels can be stored and used. They also discussed whether recipient verification was needed for Hepatitis B core antibody status since positive donor extra vessels in this situation can be stored and used. It was discussed that when using these extra vessels in a secondary recipient it is often an emergent situation and the use is often life or organ saving and that the recipient status will not be a deciding factor in their use. The Committee decided to not require recipient verification of infectious disease results. Donor infectious disease result verification will be modified from "all" to hepatitis B (HBV) and hepatitis C (HCV) results when using in secondary recipients or procedures other than the original transplant.

The Committee was shown discrepancies in infectious disease testing names. To achieve consistency in some donor forms and the extra vessels labels, the term anti-HBc is proposed be used to reflect HBV core antibody results. This is the standard term used by the Centers for Disease Control and Prevention (CDC) and is recommended to avoid confusion with surface antibody or antigen shorthand terms. The Committee agreed with this change.

The Committee finished reviewing all proposed policy language with attention to post public comment edits.

The Committee also reviewed the proposed business requirements for proposed information technology (IT) changes. These include changes to DonorNet, TIEDI, and TransNet. Strongyloides will be added to DonorNet infectious disease screening tab (as an optional test result). The "unknown" test result option for donor forms will be retired. In TIEDI, OPOs will be given access to extra vessels dispositions for those they have recovered. The Deceased Donor Registration (DDR) form will also have Strongyloides added and unknown retired. In TransNet, programming will be done for the new extra vessels label requirements. A bar code will be added to allow for scan access to results in DonorNet not printed on the label.

The Committee voted (17 yes, 0 no, 0 abstain) to send the extra vessels proposal to the OPTN/UNOS BOD for consideration at their June 2018 meeting.

Next steps:

- Send the proposal “Extra Vessels: Reducing Reporting Burdens and Clarifying Policies” to the OPTN/UNOS Board of Directors for consideration and approval
- Submit research data request to HRSA to analyze the frequency of extra vessels used in living donor procedures and where extra vessels are sent without an organ
- Develop proposal for a policy definition for recovery date for fall 2018 public comment

5. TransNet update

Mandatory use of TransNet for OPOs continues to be monitored. The Committee continues to follow and promote TransNet pilot use among transplant hospitals.

Data summary:

TransNet data use among OPOs was reviewed. There were no patterns of non-use identified among OPOs. The staff acknowledged some versioning issues were likely related to some dips in use in November but that overall data use is in the high 90th percentile and has largely remained at that level following mandatory implementation.

Summary of discussion:

Staff shared that fixes needed since the operating systems changes in November have been released. There will likely be more release. Transplant hospital pilots continue, however, there have not been many new or full adapters as the process to gain approvals at the hospital level take significant effort and time.

Next steps:

The TransNet Work Group will continue to meet monthly. They will consider extra vessels label design options for TransNet and make recommendations to the full Committee.

6. Patient Safety Data

The Committee conducted their semi-annual review of aggregate patient safety situation event data reported to the OPTN.

Data summary:

In 2017, there were 268 events reported and 172 were reported online through the Improving Patient Safety (IPS) portal. Nearly half (n= 125) were self-reported. Aggregate data on common categories such as transplant process/procedure, data entry, living donor, and communication events were reviewed in more detail. There were 44 non-recoveries of an organ associated with an event during 2016-2017. The majority were living donor aborted procedures. There were 31 discard events most commonly related to transplant process/procedure situations and packaging/shipping issues during that time frame. In addition, there were 24 events associated with additional cold ischemia time. Most were due to packaging/shipping and transportation issues.

Summary of discussion:

The Committee reviewed the data and identified questions and events related to the transplant process/procedure category that they will discuss further when considering educational referrals.

Next steps:

The Committee will continue to review patient safety event aggregate data every six months as part of a standing data request.

7. Policy Evaluations

The Committee reviewed data from the ABO policy evaluation.

Data summary:

Patient safety situation data potentially related to ABO processes were reviewed. There were some process situations identified related to verification and identification. Data related to ABO data entry as well as packaging, labeling, and testing were also discussed. The majority of reports in these areas were not ABO related. Data were reviewed for candidates transplanted that did not appear on a match run. There were 97 cases between July 1, 2016 and December 31, 2017 representing 0.2% of all deceased donor transplants performed. The majority were directed donations (n= 77). Candidate and donor ABO discrepancies were also reviewed. There were 0.1% discrepancies on the candidate side and 0.4% discrepancies on the donor side.

Summary of discussion:

The Committee discussed these data during patient safety advisory group update in conjunction with educational referrals from the MPSC and Member Quality (MQ).

Next steps:

The Committee will continue periodic updates of the ABO policy evaluation.

8. Patient Safety Advisory Group Update

The Patient Safety Advisory Group continued its review of patient safety data and educational referrals to develop educational products for the transplant community to help share effective practices and preventive strategies. The most recent module released was related to post-transplant testing following transplantation of increased risk organs.

Summary of discussion:

The full Committee reviewed several items referred that were related to ABO and subtyping process and procedures. A subtyping issue was brought up on a national webinar regarding discrepant results. Other situations involved process gaps in patient identification and following established verification procedures. In addition, documentation issues continue to emerge with ABO verification. The Committee discussed how these types of errors can occur. The referrals will be further evaluated and member education developed by the Patient Safety Advisory Group.

Next steps:

The Patient Safety Advisory Group will further evaluate the referrals. They will consider if any warrant policy, guidance, or programming prevention strategies and report back to the full Committee. They will work with Professional Education to develop a safety education product based on the referral.

9. Transportation Survey and other new project ideas

The Committee has developed a poster accepted for the Transplant Management Forum (TMF) that summarizes the transportation survey data results.

Next steps:

Discuss transportation survey results at the TMF poster session.

Upcoming Meeting

- May 24, 2018

Attendance

- **(Sub)Committee Members**
 - First Name Last Name
 - First Name Last Name
- **HRSA Representatives**
 - First Name Last Name
- **SRTR Staff**
 - First Name Last Name
- **OPTN/UNOS Staff**
 - First Name Last Name
- **Other Attendees**
 - First Name Last Name